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In re Patent Application of: David B. Krig et al.

Title: METHOD AND APPARATUS FOR TREATING IRREGULAR VENTRICULAR CONTRACTIONS  
SUCH AS DURING ATRIAL ARRHYTHMIA

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- ☒ Utility Patent Application under 37 CFR § 1.53(b) comprising:
- ☒ Specification ( 42 pgs, including claims numbered 1 through 91 and a 1 page Abstract).
  - ☒ Formal Drawing(s) ( 14 sheets).
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  - ☒ Check in the amount of \$2,350.00 to pay the filing fee.
- ☒ Assignment of the invention to Cardiac Pacemakers, Inc. ( 4 pgs) and Recordation Form Cover Sheet.
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UNITED STATES PATENT APPLICATION

**METHOD AND APPARATUS FOR TREATING IRREGULAR  
VENTRICULAR CONTRACTIONS SUCH AS DURING ATRIAL  
ARRHYTHMIA**

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[illegible]

5           This application is related to the following co-pending, commonly assigned  
patent applications: “Cardiac Rhythm Management System Promoting Atrial  
Pacing,” serial number \_\_\_\_\_, (Attorney Docket No. 00279.113US1);  
“Cardiac Rhythm Management System With Atrial Shock Timing Optimization,”  
serial number \_\_\_\_\_, (Attorney Docket No. 00279.142US1); and “System  
10 Providing Ventricular Pacing and Biventricular Coordination,” serial number  
\_\_\_\_\_, (Attorney Docket No. 00279.160US1); each of which are filed on  
even date herewith, each of which disclosure is herein incorporated by reference in  
its entirety.

The present system relates generally to cardiac rhythm management systems and particularly, but not by way of limitation, to a method and apparatus for treating irregular ventricular contractions, such as during an atrial arrhythmia.

When functioning properly, the human heart maintains its own intrinsic rhythm, and is capable of pumping adequate blood throughout the body's circulatory system. However, some people have irregular cardiac rhythms, referred to as cardiac arrhythmias. Such arrhythmias result in diminished blood circulation. One mode of treating cardiac arrhythmias uses drug therapy. Drugs are often effective at restoring normal heart rhythms. However, drug therapy is not always effective for treating arrhythmias of certain patients. For such patients, an alternative mode of treatment is needed. One such alternative mode of treatment includes the use of a cardiac rhythm management system. Such systems are often implanted in the patient and deliver therapy to the heart.

Cardiac rhythm management systems include, among other things, pacemakers, also referred to as pacers. Pacers deliver timed sequences of low energy electrical stimuli, called pace pulses, to the heart, such as via an intravascular leadwire or catheter (referred to as a "lead") having one or more electrodes disposed in or about the heart. Heart contractions are initiated in response to such pace pulses (this is referred to as "capturing" the heart). By properly timing the delivery of pace pulses, the heart can be induced to contract in proper rhythm, greatly improving its efficiency as a pump. Pacers are often used to treat patients with bradyarrhythmias, that is, hearts that beat too slowly, or irregularly.

Cardiac rhythm management systems also include cardioverters or defibrillators that are capable of delivering higher energy electrical stimuli to the heart. Defibrillators are often used to treat patients with tachyarrhythmias, that is, hearts that beat too quickly. Such too-fast heart rhythms also cause diminished blood circulation because the heart isn't allowed sufficient time to fill with blood before contracting to expel the blood. Such pumping by the heart is inefficient. A defibrillator is capable of delivering an high energy electrical stimulus that is sometimes referred to as a defibrillation countershock. The countershock interrupts the tachyarrhythmia, allowing the heart to reestablish a normal rhythm for the efficient pumping of blood. In addition to pacers, cardiac rhythm management systems also include, among other things, pacer/defibrillators that combine the functions of pacers and defibrillators, drug delivery devices, and any other implantable or external systems or devices for diagnosing or treating cardiac arrhythmias.

One problem faced by cardiac rhythm management systems is the proper treatment of ventricular arrhythmias that are caused by atrial tachyarrhythmias such as atrial fibrillation. Atrial fibrillation is a common cardiac arrhythmia which reduces the pumping efficiency of the heart, though not to as great a degree as in ventricular fibrillation. However, this reduced pumping efficiency requires the ventricle to work harder, which is particularly undesirable in sick patients that cannot tolerate additional stresses. As a result of atrial fibrillation, patients may be

required to limit their activity and exercise.

Although atrial fibrillation, by itself, is usually not life-threatening, prolonged atrial fibrillation may be associated with strokes, which are thought to be caused by blood clots forming in areas of stagnant blood flow. Treating such blood  
5 clots requires the use of anticoagulants. Atrial fibrillation may also cause pain, dizziness, and other irritation to the patient.

An even more serious problem, however, is that atrial fibrillation may induce irregular ventricular heart rhythms by processes that are yet to be fully understood. Such induced ventricular arrhythmias compromise pumping efficiency even more  
10 drastically than atrial arrhythmias. For these and other reasons, there is a need for a method and apparatus for treating irregular ventricular contractions during atrial arrhythmias such as atrial fibrillation.

### **Summary of the Invention**

15 The present system provides a method and apparatus for treating irregular ventricular contractions, such as during atrial arrhythmias (e.g., atrial fibrillation), or otherwise. The present system provides many advantages. Among other things, it is capable of treating irregular ventricular heart contractions, such as during atrial tachyarrhythmias. It provides a first indicated pacing rate that increases for sensed  
20 ventricular beats and decreases for paced ventricular beats. The system delivers more pacing during irregular sensed beats (such as during atrial tachyarrhythmias including atrial fibrillation or the like) and less pacing when sensed beats are regular. In a stable heart, the first indicated pacing rate is typically less than the intrinsic heart rate. This avoids unnecessary pacing of the heart when heart rhythms  
25 are substantially stable, allowing the heart to beat normally and at its own intrinsic heart rate.

One aspect of the system permits it to avoid rapid changes in heart rate, and to keep heart rate within acceptable upper and lower limits. The system allows the rate to become more regular and to approach a stable rhythm. This provides  
30 improved comfort of the patient experiencing irregular ventricular contractions. In a

US 2015/0199990 A1

further embodiment, the system includes a second indicated pacing rate, such as a sensor-indicated rate, and provides pacing therapy based on both the first and second indicated pacing rates. Other aspects of the invention will be apparent on reading the following detailed description of the invention and viewing the drawings that form a part thereof.

In one embodiment, the system obtains V-V intervals between ventricular beats. A first indicated pacing interval is computed based at least partially on a most recent V-V interval duration and a previous value of the first indicated pacing interval. Pacing therapy is provided based on the first indicated pacing interval.

10 In a further embodiment, the first indicated pacing interval is adjusted by an amount based at least on the most recent V-V interval duration and the previous value of the first indicated pacing interval, if the most recent V-V interval is concluded by an intrinsic beat. If, however, the most recent V-V interval is concluded by a paced beat, then the first indicated pacing interval is increased by an amount based at least on the most recent V-V interval duration and the previous value of the first indicated pacing interval.

15 In another embodiment, the system detects an atrial tachyarrhythmia. The system obtains V-V intervals between ventricular beats. A first indicated pacing interval is computed based at least partially on a most recent V-V interval duration and a previous value of the first indicated pacing interval. Pacing therapy is provided based on the first indicated pacing interval, if the atrial tachyarrhythmia is present.

20 One embodiment provides a cardiac rhythm management system that includes, among other things, a ventricular sensing circuit, a controller, and a ventricular therapy circuit. The controller includes a V-V interval timer, a first register, for storing information associated with a first indicated pacing interval, and a filter that updates the first indicated pacing interval based on the V-V interval timer and the information stored in the first register. Other aspects of the invention will be apparent on reading the following detailed description of the invention and viewing the drawings that form a part thereof.

25 30

### **Brief Description of the Drawings**

In the drawings, like numerals describe substantially similar components throughout the several views. Like numerals having different letter suffixes represent different instances of substantially similar components.

5        Figure 1 is a schematic drawing illustrating generally one embodiment of portions of a cardiac rhythm management system and an environment in which it is used.

Figure 2 is a schematic drawing illustrating one embodiment of a cardiac rhythm management device coupled by leads to a heart.

10       Figure 3 is a schematic diagram illustrating generally one embodiment of portions of a cardiac rhythm management device coupled to a heart.

Figure 4 is a schematic diagram illustrating generally one embodiment of a controller.

15       Figure 5 is a schematic diagram illustrating generally one conceptualization of portions of a controller.

Figure 6 is a signal flow diagram illustrating generally one conceptual embodiment of operating a filter.

Figure 7 is a signal flow diagram illustrating generally another conceptualization of operating the filter.

20       Figure 8 is a signal flow diagram illustrating generally a further conceptualization of operating the filter.

Figure 9 is a schematic diagram illustrating generally another conceptualization of portions of a controller.

25       Figure 10 is a schematic diagram illustrating generally a further conceptualization of portions of a controller.

Figure 11 is a graph illustrating generally one embodiment of operating a filter to provide a first indicated pacing rate, such as a VRR indicated rate, for successive ventricular heart beats.

30       Figure 12 is a graph illustrating generally another embodiment of operating a filter to provide the first indicated pacing rate, such as a VRR indicated rate, and

delivering therapy based on the first indicated pacing rate and based on a second indicated pacing rate, such as a sensor indicated rate.

Figure 13 is a graph illustrating generally another illustrative example of heart rate vs. time according to a VRR algorithm spreadsheet simulation.

- 5        Figure 14 is a graph illustrating generally one embodiment of using at least one of coefficients  $a$  and  $b$  as a function of heart rate (or a corresponding time interval).

### **Detailed Description**

- 10        In the following detailed description, reference is made to the accompanying drawings which form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that the embodiments may be combined, or that  
15        other embodiments may be utilized and that structural, logical and electrical changes may be made without departing from the spirit and scope of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims and their equivalents. In the drawings, like numerals describe substantially similar  
20        components throughout the several views. Like numerals having different letter suffixes represent different instances of substantially similar components.

- The present methods and apparatus will be described in applications involving implantable medical devices including, but not limited to, implantable cardiac rhythm management systems such as pacemakers, cardioverter/defibrillators,  
25        and pacer/defibrillators. However, it is understood that the present methods and apparatus may be employed in unimplanted devices, including, but not limited to, external pacemakers, cardioverter/defibrillators, pacer/defibrillators, monitors, programmers and recorders.

### **Problems Associated With Atrial Arrhythmias**

- 30        As stated earlier, one potential cause of irregularity of ventricular



contractions arises during atrial tachyarrhythmias, such as atrial fibrillation. During atrial fibrillation, irregular ventricular contractions may be caused by a conducted atrial tachyarrhythmia, then pacing the ventricle will regularize the ventricular heart rate by establishing retrograde conduction from the ventricle. This, in turn, is  
5 believed to block forward conduction of atrial signals through the atrioventricular (A-V) node. As a result, irregular atrial signals do not trigger resulting irregular ventricular contractions.

One therapy for treating irregular ventricular contractions during atrial fibrillation is to increase the ventricular heart rate by pacing the ventricle at a higher  
10 rate than the unpaced (intrinsic) ventricular heart rate. Such therapy is believed to decrease the discomfort experienced by the patient having atrial arrhythmia because it regulates the ventricular contractions to avoid short periods between contractions and/or long periods without a contraction. Such therapy is also believed to decrease the ability of the atrial fibrillation to induce irregular ventricular contractions.

15 An increase in rate of ventricular contractions, however, must be done carefully to avoid pacing the heart at an unnecessarily high rate. Furthermore, such a therapy should not impose pacing where normal or “intrinsic” heart pacing is adequate such as, for example, when atrial tachyarrhythmias no longer cause disorder of ventricular contractions. As long as the heart is actively paced, it may be  
20 difficult or impossible to determine when to cease such a therapy. One advantage of the present system is that it allows intrinsic ventricular rhythms, if such rhythms are regular, but provides pacing that stabilizes ventricular rhythms if they become irregular, as discussed below.

#### General System Overview and Examples

25 This document describes, among other things, a cardiac rhythm management system providing a method and apparatus for treating irregular ventricular contractions during atrial arrhythmia. Figure 1 is a schematic drawing illustrating, by way of example, but not by way of limitation, one embodiment of portions of a cardiac rhythm management system 100 and an environment in which it is used. In  
30 Figure 1, system 100 includes an implantable cardiac rhythm management device

105, also referred to as an electronics unit, which is coupled by an intravascular endocardial lead 110, or other lead, to a heart 115 of patient 120. System 100 also includes an external programmer 125 providing wireless communication with device 105 using a telemetry device 130. Catheter lead 110 includes a proximal end 5 135, which is coupled to device 105, and a distal end 140, which is coupled to one or more portions of heart 115.

Figure 2 is a schematic drawing illustrating, by way of example, but not by way of limitation, one embodiment of device 105 coupled by leads 110A-B to heart 115, which includes a right atrium 200A, a left atrium 200B, a right ventricle 205A, 10 a left ventricle 205B, and a coronary sinus 220 extending from right atrium 200A. In this embodiment, atrial lead 110A includes electrodes (electrical contacts) disposed in, around, or near an atrium 200 of heart 115, such as ring electrode 225 and tip electrode 230, for sensing signals and/or delivering pacing therapy to the atrium 200. Lead 110A optionally also includes additional electrodes, such as for 15 delivering atrial and/or ventricular cardioversion/defibrillation and/or pacing therapy to heart 115.

In Figure 2, a ventricular lead 110B includes one or more electrodes, such as tip electrode 235 and ring electrode 240, for delivering sensing signals and/or delivering pacing therapy. Lead 110B optionally also includes additional electrodes, 20 such as for delivering atrial and/or ventricular cardioversion/defibrillation and/or pacing therapy to heart 115. Device 105 includes components that are enclosed in a hermetically-sealed can 250. Additional electrodes may be located on the can 250, or on an insulating header 255, or on other portions of device 105, for providing unipolar pacing and/or defibrillation energy in conjunction with the electrodes 25 disposed on or around heart 115. Other forms of electrodes include meshes and patches which may be applied to portions of heart 115 or which may be implanted in other areas of the body to help “steer” electrical currents produced by device 105. The present method and apparatus will work in a variety of configurations and with a variety of electrical contacts or “electrodes.”

### Example Cardiac Rhythm Management Device

Figure 3 is a schematic diagram illustrating generally, by way of example, but not by way of limitation, one embodiment of portions of device **105**, which is coupled to heart **115**. Device **105** includes a power source **300**, an atrial sensing circuit **305**, a ventricular sensing circuit **310**, a ventricular therapy circuit **320**, and a controller **325**.

Atrial sensing circuit **305** is coupled by atrial lead **110A** to heart **115** for receiving, sensing, and/or detecting electrical atrial heart signals. Such atrial heart signals include atrial activations (also referred to as atrial depolarizations or P-waves), which correspond to atrial contractions. Such atrial heart signals include normal atrial rhythms, and abnormal atrial rhythms including atrial tachyarrhythmias, such as atrial fibrillation, and other atrial activity. Atrial sensing circuit **305** provides one or more signals to controller **325**, via node/bus **327**, based on the received atrial heart signals. Such signals provided to controller **325** indicate, among other things, the presence of atrial fibrillation.

Ventricular sensing circuit **310** is coupled by ventricular lead **110B** to heart **115** for receiving, sensing, and/or detecting electrical ventricular heart signals, such as ventricular activations (also referred to as ventricular depolarizations or R-waves), which correspond to ventricular contractions. Such ventricular heart signals include normal ventricular rhythms, and abnormal ventricular rhythms, including ventricular tachyarrhythmias, such as ventricular fibrillation, and other ventricular activity, such as irregular ventricular contractions resulting from conducted signals from atrial fibrillation. Ventricular sensing circuit **310** provides one or more signals to controller **325**, via node/bus **327**, based on the received ventricular heart signals. Such signals provided to controller **325** indicate, among other things, the presence of ventricular depolarizations, whether regular or irregular in rhythm.

Ventricular therapy circuit **320** provides ventricular pacing therapy, as appropriate, to electrodes located at or near one of the ventricles **205** of heart **115** for obtaining resulting evoked ventricular depolarizations. In one embodiment, ventricular therapy circuit **320** also provides cardioversion/defibrillation therapy, as

appropriate, to electrodes located at or near one of the ventricles **205** of heart **115**, for terminating ventricular fibrillation and/or other ventricular tachyarrhythmias.

Controller **325** controls the delivery of therapy by ventricular therapy circuit **320** and/or other circuits, based on heart activity signals received from atrial sensing circuit **305** and ventricular sensing circuit **310**, as discussed below. Controller **325** includes various modules, which are implemented either in hardware or as one or more sequences of steps carried out on a microprocessor or other controller. Such modules are illustrated separately for conceptual clarity; it is understood that the various modules of controller **325** need not be separately embodied, but may be combined and/or otherwise implemented, such as in software/firmware.

In general terms, sensing circuits **305** and **310** sense electrical signals from heart tissue in contact with the catheter leads **110A-B** to which these sensing circuits **305** and **310** are coupled. Sensing circuits **305** and **310** and/or controller **325** process these sensed signals. Based on these sensed signals, controller **325** issues control signals to therapy circuits, such as ventricular therapy circuit **320**, if necessary, for the delivery of electrical energy (e.g., pacing and/or defibrillation pulses) to the appropriate electrodes of leads **110A-B**. Controller **325** may include a microprocessor or other controller for execution of software and/or firmware instructions. The software of controller **325** may be modified (e.g., by remote external programmer **105**) to provide different parameters, modes, and/or functions for the implantable device **105** or to adapt or improve performance of device **105**.

In one further embodiment, one or more sensors, such as sensor **330**, may serve as inputs to controller **325** for adjusting the rate at which pacing or other therapy is delivered to heart **115**. One such sensor **330** includes an accelerometer that provides an input to controller **325** indicating increases and decreases in physical activity, for which controller **325** increases and decreases pacing rate, respectively. Another such sensor includes an impedance measurement, obtained from body electrodes, which provides an indication of increases and decreases in the patient's respiration, for example, for which controller **325** increases and decreases pacing rate, respectively. Any other sensor **330** providing an indicated pacing rate

can be used.

Figure 4 is a schematic diagram illustrating generally, by way of example, but not by way of limitation, one embodiment of controller 325 that includes several different inputs to modify the rate at which pacing or other therapy is delivered. For example, Input #1 may provide information about left ventricular rate, Input #2 may provide an accelerometer-based indication of activity, and Input #3 may provide an impedance-based indication of respiration, such as minute ventilation. Based on at least one of these and/or other inputs, controller 325 provides an output indication of pacing rate as a control signal delivered to a therapy circuit, such as to ventricular therapy circuit 320. Ventricular therapy circuit 320 issues pacing pulses based on one or more such control signals received from controller 325. Control of the pacing rate may be performed by controller 325, either alone or in combination with peripheral circuits or modules, using software, hardware, firmware, or any combination of the like. The software embodiments provide flexibility in how inputs are processed and may also provide the opportunity to remotely upgrade the device software while still implanted in the patient without having to perform surgery to remove and/or replace the device 105.

#### Controller Example 1

Figure 5 is a schematic diagram illustrating generally, by way of example, but not by way of limitation, one conceptualization of portions of controller 325. At least one signal from ventricular sensing circuit 310 is received by ventricular event module 500, which recognizes the occurrence of ventricular events included within the signal. Such events are also referred to as “beats,” “activations,” “depolarizations,” “QRS complexes,” “R-waves,” “contractions.” Ventricular event module 500 detects intrinsic events (also referred to as sensed events) from the signal obtained from ventricular sensing circuit 310. Ventricular event module 500 also detects evoked events (resulting from a pace) either from the signal obtained from ventricular sensing circuit 310, or preferably from a ventricular pacing control signal obtained from pacing control module 505, which also triggers the delivery of a pacing stimulus by ventricular therapy circuit 320. Thus, ventricular events

include both intrinsic/sensed events and evoked/paced events.

A time interval between successive ventricular events, referred to as a V-V interval, is recorded by a first timer, such as V-V interval timer **510**. A filter **515** computes a "first indicated pacing interval," i.e., one indication of a desired time interval between ventricular events or, stated differently, a desired ventricular heart rate. The first indicated pacing interval is also referred to as a ventricular rate regularization (VRR) indicated pacing interval. In various embodiments, filter **515** includes an averager, a weighted averager, a median filter, an infinite (IIR) filter, a finite impulse response (FIR) filter, or any other analog or digital signal processing circuit providing the desired signal processing described more particularly below.

In one embodiment, filter **515** computes a new value of the first indicated pacing interval based on the duration of the most recent V-V interval recorded by timer **510** and on a previous value of the first indicated pacing interval stored in first indicated pacing interval register **520**. Register **520** is then updated by storing the newly computed first indicated pacing interval in register **520**. Based on the first indicated pacing interval stored in register **520**, pacing control module **505** delivers control signals to ventricular therapy circuit **320** for delivering therapy, such as pacing stimuli, at the VRR-indicated ventricular heart rate corresponding to the inverse of the duration of the first indicated pacing interval.

#### Filter Example 1

In general terms, for one embodiment, device **105** obtains V-V intervals between successive sensed or evoked ventricular beats. Device **105** computes a new first indicated pacing interval based at least in part on the duration of the most recent V-V interval and a previous value of the first indicated pacing interval. Device **105** provides pacing therapy delivered at a rate corresponding to the inverse of the duration of the first indicated pacing interval.

Figure 6 is a signal flow diagram illustrating generally, by way of example, but not by way of limitation, one embodiment of operating filter **515**. Upon the occurrence of a sensed or evoked ventricular beat, timer **510** provides filter **515** with the duration of the V-V interval concluded by that beat, which is referred to as the

most recent V-V interval ( $VV_n$ ). Filter **515** also receives the previous value of the first indicated pacing interval ( $T_{n-1}$ ) stored in register **520**. The most recent V-V interval  $VV_n$  and the previous value of the first indicated pacing interval  $T_{n-1}$  are each scaled by respective constants  $A$  and  $B$ , and then summed to obtain a new value of the first indicated pacing interval ( $T_n$ ), which is stored in register **520** and provided to pacing control module **505**. In one embodiment, the coefficients  $A$  and  $B$  are different values, and are either programmable, variable, or constant.

If no ventricular beat is sensed during the new first indicated pacing interval  $T_n$ , which is measured as the time from the occurrence of the ventricular beat concluding the most recent V-V interval  $VV_n$ , then pacing control module **505** instructs ventricular therapy circuit **320** to deliver a ventricular pacing pulse upon the expiration of the new first indicated pacing interval  $T_n$ . In one embodiment, operation of the filter is described by  $T_n = A \cdot VV_n + B \cdot T_{n-1}$ , where  $A$  and  $B$  are coefficients (also referred to as “weights”),  $VV_n$  is the most recent V-V interval duration, and  $T_{n-1}$  is the previous value of the first indicated pacing interval.

Initialization of filter **515** includes seeding the filter by storing, in register **520**, an initial interval value. In one embodiment, register **520** is initialized to an interval value corresponding to a lower rate limit (LRL), i.e., a minimum rate at which pacing pulses are delivered by device **105**. Register **520** could alternatively be initialized with any other suitable value.

#### Filter Example 2

In one embodiment, operation of filter **515** is based on whether the beat concluding the most recent V-V interval  $VV_n$  is a sensed/intrinsic beat or a paced/evoked beat. In this embodiment, the pacing control module **505**, which controls the timing and delivery of pacing pulses, provides an input to filter **515** that indicates whether the most recent V-V interval  $VV_n$  was concluded by an evoked beat initiated by a pacing stimulus delivered by device **105**, or was concluded by an intrinsic beat sensed by ventricular sensing circuit **310**.

In general terms, if the most recent V-V interval  $VV_n$  is concluded by a sensed/intrinsic beat, then filter **515** provides a new first indicated pacing interval  $T_n$

that is adjusted from the value of the previous first indicated pacing interval  $T_{n-1}$  such as, for example, decreased by an amount that is based at least partially on the duration of the most recent V-V interval  $VV_n$  and on the duration of the previous value of the first indicated pacing interval  $T_{n-1}$ . If, however, the most recent V-V interval  $VV_n$  is concluded by a paced/evoked beat, then filter 515 provides a new first indicated pacing interval  $T_n$  that is increased from the value of the previous first indicated pacing interval  $T_{n-1}$ , such as, for example, by an amount that is based at least partially on the duration of the most recent V-V interval  $VV_n$  and on the duration of the previous value of the first indicated pacing interval  $T_{n-1}$ . If no ventricular beat is sensed during the new first indicated pacing interval  $T_n$ , which is measured as the time from the occurrence of the ventricular beat concluding the most recent V-V interval  $VV_n$ , then pacing control module 505 instructs ventricular therapy circuit 320 to deliver a ventricular pacing pulse upon the expiration of the new first indicated pacing interval  $T_n$ .

Figure 7 is a signal flow diagram, illustrating generally, by way of example, but not by way of limitation, another conceptualization of operating filter 515, with certain differences from Figure 6 more particularly described below. In this embodiment, the pacing control module 505, which controls the timing and delivery of pacing pulses, provides an input to filter 515 that indicates whether the most recent V-V interval  $VV_n$  was concluded by an evoked beat initiated by a pacing stimulus delivered by device 105, or was concluded by an intrinsic beat sensed by ventricular sensing circuit 310.

If the most recent V-V interval  $VV_n$  was concluded by an intrinsic beat, then the most recent V-V interval  $VV_n$  and the previous value of the first indicated pacing interval  $T_{n-1}$  are each scaled by respective constants  $A$  and  $B$ , and then summed to obtain the new value of the first indicated pacing interval  $T_n$ , which is stored in register 520 and provided to pacing control module 505. Alternatively, if the most recent V-V interval  $VV_n$  was concluded by a evoked/paced beat, then the most recent V-V interval  $VV_n$  and the previous value of the first indicated pacing interval  $T_{n-1}$  are each scaled by respective constants  $C$  and  $D$ , and then summed to obtain the new



value of the first indicated pacing interval  $T_n$ , which is stored in register **520** and provided to pacing control module **505**. In one embodiment, the coefficients  $C$  and  $D$  are different from each other, and are either programmable, variable, or constant. In a further embodiment, the coefficient  $C$  is a different value from the coefficient  $A$ , and/or the coefficient  $D$  is a different value than the coefficient  $B$ , and these coefficients are either programmable, variable, or constant. In another embodiment, the coefficient  $D$  is the same value as the coefficient  $B$ .

In one embodiment, operation of filter **515** is described by  $T_n = A \cdot VV_n + B \cdot T_{n-1}$ , if  $VV_n$  is concluded by an intrinsic beat, and is described by  $T_n = C \cdot VV_n + D \cdot T_{n-1}$ , if  $VV_n$  is concluded by a paced beat, where  $A$ ,  $B$ ,  $C$  and  $D$  are coefficients (also referred to as “weights”),  $VV_n$  is the most recent V-V interval duration,  $T_n$  is the new value of the first indicated pacing interval, and  $T_{n-1}$  is the previous value of the first indicated pacing interval. If no ventricular beat is sensed during the new first indicated pacing interval  $T_n$ , which is measured as the time from the occurrence of the ventricular beat concluding the most recent V-V interval  $VV_n$ , then pacing control module **505** instructs ventricular therapy circuit **320** to deliver a ventricular pacing pulse upon the expiration of the new first indicated pacing interval  $T_n$ .

### Filter Example 3

In another embodiment, these coefficients can be more particularly described using an intrinsic coefficient ( $a$ ), a paced coefficient ( $b$ ), and a weighting coefficient ( $w$ ). In one such embodiment,  $A = a \cdot w$ ,  $B = (1-w)$ ,  $C = b \cdot w$ , and  $D = (1-w)$ . In one example, operation of the filter **515** is described by  $T_n = a \cdot w \cdot VV_n + (1-w) \cdot T_{n-1}$ , if  $VV_n$  is concluded by an intrinsic beat, otherwise is described by  $T_n = b \cdot w \cdot VV_n + (1-w) \cdot T_{n-1}$ , if  $VV_n$  is concluded by a paced beat, as illustrated generally, by way of example, but not by way of limitation, in the signal flow graph of Figure 8. If no ventricular beat is sensed during the new first indicated pacing interval  $T_n$ , which is measured as the time from the occurrence of the ventricular beat concluding the most recent V-V interval  $VV_n$ , then pacing control module **505** instructs ventricular therapy circuit **320** to deliver a ventricular pacing pulse upon the expiration of the new first indicated pacing interval  $T_n$ . In one embodiment, the coefficients  $a$  and  $b$  are

different from each other, and are either programmable, variable, or constant.

The above-described parameters (e.g.,  $A, B, C, D, a, b, w$ ) are stated in terms of time intervals (e.g.,  $VV_n, T_n, T_{n-1}$ ). However, an alternate system may produce results in terms of rate, rather than time intervals, without departing from the present method and apparatus. In one embodiment, weighting coefficient  $w$ , intrinsic coefficient  $a$ , and paced coefficient  $b$ , are variables. Different selections of  $w, a$ , and  $b$ , will result in different operation of the present method and apparatus. For example, as  $w$  increases the weighting effect of the most recent V-V interval  $VV_n$  increases and the weighting effect of the previous first indicated pacing rate  $T_{n-1}$  decreases. In one embodiment,  $w = 1/16 = 0.0625$ . In another embodiment,  $w = 1/32$ . Another possible range for  $w$  is from  $w = 1/2$  to  $w = 1/1024$ . A further possible range for  $w$  is from  $w \approx 0$  to  $w \approx 1$ . Other values of  $w$ , which need not include division by powers of two, may be substituted without departing from the present method and apparatus.

In one embodiment, intrinsic coefficient  $a$ , is selected to be greater than 0.5, or to be greater than 1.0. In one example, the intrinsic coefficient  $a$  is selected to be lesser in value than the pacing coefficient  $b$ . In one example,  $a \approx 1.1$  and  $b \approx 1.2$ . In another embodiment  $a = 0.9$  and  $b = 1.1$ . One possible range for  $a$  is from  $a = 0.5$  to  $a = 2.0$ , and for  $b$  is from  $b = 1.0$  to  $b = 3.0$ . The coefficients may vary without departing from the present method and apparatus.

In one embodiment, for  $b > 1$  and for substantially regular V-V intervals, filter 515 provides a new first indicated pacing interval  $T_n$  that is at least slightly longer than the expected intrinsic V-V interval being measured by timer 515. Thus, if the intrinsic V-V interval being timed is consistent with the duration of previously received V-V intervals, then filter 515 avoids triggering a pacing stimulus. In such a case, a pacing pulse is delivered only if the presently timed V-V interval becomes longer than the previous substantially constant V-V intervals. In general terms, filter 515 operates so that pacing pulses are typically inhibited if the ventricular rate is substantially constant. However, if the measured V-V intervals become irregular, then filter 515 operates, over a period of one or several such V-V intervals, to

shorten the first indicated pacing interval  $T_n$  so that pacing stimuli are being delivered.

According to one aspect of the invention, it is believed that if the irregular V-V intervals are caused by a conducted atrial tachyarrhythmia, then pacing the ventricle will regularize the ventricular heart rate by establishing retrograde conduction from the ventricle. This, in turn, blocks forward conduction of atrial signals through the atrioventricular (A-V) node. As a result, irregular atrial signals do not trigger resulting irregular ventricular contractions. According to another aspect of the invention, however, this method and apparatus will not introduce pacing pulses until the heartbeat becomes irregular. Therefore, the heart is assured to pace at its intrinsic rate when regular ventricular contractions are sensed.

#### Controller Example 2

Figure 9 is a schematic diagram illustrating generally, by way of example, but not by way of limitation, another conceptualization of portions of controller 325, with certain differences from Figure 5 more particularly described below. In Figure 9, controller 325 receives from sensor 330 a signal including information from which a physiologically desired heart rate (e.g., based on the patient's activity, respiration, or any other suitable indicator of metabolic need) can be derived. The sensor signal is digitized by an A/D converter 900. The digitized signal is processed by a sensor rate module 905, which computes a desired heart rate that is expressed in terms of a second indicated pacing interval stored in register 910.

Pacing control module 505 delivers a control signal, which directs ventricular therapy circuit 320 to deliver a pacing pulse, based on either (or both) of the first or second indicated pacing intervals, stored in registers 520 and 910, respectively, or both. In one embodiment, pacing control module 505 includes a selection module 915 that selects between the new first indicated pacing interval  $T_n$  and the sensor-based second indicated pacing interval.

In one embodiment, selection module 915 selects the shorter of the first and second indicated pacing intervals as the selected indicated pacing interval  $S_n$ . If no ventricular beat is sensed during the selected indicated pacing interval  $S_n$ , which is

measured as the time from the occurrence of the ventricular beat concluding the most recent V-V interval  $VV_n$ , then pacing control module **505** instructs ventricular therapy circuit **320** to deliver a ventricular pacing pulse upon the expiration of the selected indicated pacing interval  $S_n$ .

5           In general terms, for this embodiment, the ventricle is paced at the higher of the sensor indicated rate and the VRR indicated rate. If, for example, the patient is resting, such that the sensor indicated rate is lower than the patient's intrinsic rate, and the patient's intrinsic rate is substantially constant, then the intrinsic rate is higher than the VRR indicated rate. As a result, pacing pulses generally will not be  
10 delivered. But if, for example, the patient is resting, but with an atrial tachyarrhythmia that induces irregular ventricular contractions, then pacing pulses generally will be delivered at the VRR indicated rate. In another example, if the patient is active, such that the sensor indicated rate is higher than the VRR indicated rate, then pacing pulses generally will be delivered at the sensor indicated rate. In  
15 an alternative embodiment, the pacing rate is determined by blending the sensor indicated rate and the VRR indicated rate, rather than by selecting the higher of these two indicated rates (i.e., the shorter of the first and second indicated pacing intervals).

          In another embodiment, selection module **915** provides a selected indicated  
20 pacing interval  $S_n$  based on a blending of both the first and second indicated pacing intervals. In one such example, selection module **915** applies predetermined or other weights to the first and second indicated pacing intervals to compute the selected pacing interval  $S_n$ .

#### Controller Example 2

25           Figure **10** is a schematic diagram illustrating generally, by way of example, but not by way of limitation, another conceptualization of portions of controller **325**, with certain differences from Figure **9** more particularly described below. In Figure **10**, controller **325** includes an atrial tachyarrhythmia (AT) detection module **1000** that receives a signal from atrial sensing circuit **305**. The received signal includes  
30 information about atrial events, from which AT detection module **1000** determines

the presence or absence of one or more atrial tachyarrhythmias, such as atrial fibrillation.

In one embodiment, AT detection module **1000** provides a control signal, to pacing control module **505**, that indicates the presence or absence of an atrial tachyarrhythmia, such as atrial fibrillation. In one embodiment, selection module **915** selects between the first and second indicated pacing intervals as illustrated, by way of example, but not by way of limitation, in Table 1.

Table 1. Example Selection Based on AT Detection, 1st Indicated Pacing Interval, and 2nd Indicated Pacing Interval

<i><b>AT Present?</b></i>	<i><b>1st Indicated Pacing Interval &lt; 2nd Indicated Pacing Interval ?</b></i>	<i><b>1st Indicated Pacing Interval ≥ 2nd Indicated Pacing Interval ?</b></i>
<i><b>Yes, AT Present</b></i>	$S_n \leftarrow$ 1st Indicated Pacing Interval (i.e., VRR)	$S_n \leftarrow$ 2nd Indicated Pacing Interval (e.g., Sensor)
<i><b>No, AT not Present</b></i>	$S_n \leftarrow$ 2nd Indicated Pacing Interval (e.g., Sensor)	$S_n \leftarrow$ 2nd Indicated Pacing Interval (e.g., Sensor)

In this embodiment, if an atrial tachyarrhythmia is present and the first indicated pacing interval is shorter than the second indicated pacing interval, then selection module **915** selects the first indicated pacing interval, which is based on the VRR techniques described above, as the selected indicated pacing interval  $S_n$ . Otherwise, selection module **915** selects the second indicated pacing interval, which in one embodiment is based on the sensor indications, as the selected indicated pacing interval  $S_n$ . As discussed above, if no ventricular beat is sensed during the selected indicated pacing interval  $S_n$ , which is measured as the time from the occurrence of the ventricular beat concluding the most recent V-V interval  $VV_n$ , then pacing control module **505** instructs ventricular therapy circuit **320** to deliver a

ventricular pacing pulse upon the expiration of the selected indicated pacing interval  $S_n$ .

5 Stated differently, for this embodiment, the ventricle is paced at the VRR indicated rate only if an atrial tachyarrhythmia, such as atrial fibrillation, is present and the VRR indicated rate exceeds the sensor indicated rate. Otherwise the ventricle is paced at the sensor indicated rate. If, for example, the patient is resting, such that the sensor indicated rate is lower than the patient's intrinsic rate, and no atrial tachyarrhythmia is present, then the device will sense the intrinsic rate or will deliver ventricular paces at the lower rate limit. But if, for example, the patient is resting, but with an atrial tachyarrhythmia that induces irregular ventricular contractions, then pacing pulses generally will be delivered at the VRR indicated rate. In another example, if the patient is active, such that the sensor indicated rate is higher than the VRR indicated rate, then pacing pulses generally will be delivered at the sensor indicated rate, whether or not atrial tachyarrhythmia is present. As an alternative to the selection described with respect to Table 1, selection module 915 provides a fixed or variable weighting or blending of both the sensor-indicated rate and VRR indicated rate, such that pacing pulses are delivered based on the blended rate.

20 The second indicated pacing interval need not be based on sensor indications. In one embodiment, for example, the second indicated pacing interval tracks the sensed atrial heart rate when no atrial tachyarrhythmia is present. In this embodiment, selection module 915 performs a mode-switching function in which the first indicated pacing interval is used whenever atrial tachyarrhythmia is present and the second indicated pacing interval (e.g., atrial-tracking) is used when no atrial tachyarrhythmia is present.

25 In another embodiment, heart rate/interval is used as a trigger turn on/off use of the first indicated pacing interval (e.g., the VRR indicated pacing interval). In one example, pacing therapy is based on the first indicated pacing interval if the first indicated pacing interval is longer than a first predetermined value, and pacing therapy is substantially independent of the first indicated pacing interval if the first

indicated pacing interval is shorter than the first predetermined value. In this example, the VRR indicated pacing interval is used at low heart rates, but not at fast heart rates.

#### Filter Rate Behavior Example 1

5           Figure 11 is a graph illustrating generally, by way of example, but not by way of limitation, one embodiment of a VRR indicated rate for successive ventricular heart beats for one mode of operating filter 515. As discussed above, the VRR indicated rate is simply the frequency, between ventricular heart beats, associated with the first indicated pacing interval. Stated differently, the VRR indicated rate is the inverse of the duration of the first indicated pacing interval. If  
10           pacing is based solely on the VRR indicated rate, pacing control module 505 directs ventricular therapy circuit 320 to issue a pacing pulse after the time since the last ventricular beat equals or exceeds the first indicated pacing interval. However, as described above, in certain embodiments, pacing control module 505 directs  
15           ventricular therapy circuit 320 to issue a pacing pulse based on factors other than the VRR indicated rate such as for, example, based on the sensor indicated rate.

          In the example illustrated in Figure 11, a first sensed intrinsic ventricular beat, indicated by an "S" was detected just before expiration of the first indicated pacing interval ("VRR indicated pacing interval")  $T_0$ , as computed based on a  
20           previous ventricular beat. In one embodiment, the new VRR indicated pacing interval  $T_1$  is computed based on the duration of most recent V-V interval  $VV_1$  and a previous value of the VRR indicated pacing interval  $T_0$ , as discussed above. In this example, the new VRR indicated pacing interval  $T_1$  corresponds to a lower rate limit (LRL) time interval. In one embodiment, the allowable range of the VRR indicated  
25           pacing interval is limited so that the VRR indicated pacing interval does not exceed the duration of the LRL time interval, and so that the VRR indicated pacing interval is not shorter than the duration of an upper rate limit (URL) time interval.

          The second ventricular beat is also sensed, just before expiration of the VRR indicated pacing interval  $T_1$ . In one embodiment, the new VRR indicated pacing  
30           interval  $T_2$  is computed based on the duration of most recent V-V interval  $VV_2$  and a

previous value of the VRR indicated pacing interval,  $T_1$ , as discussed above. The first and second ventricular beats represent a stable intrinsic rhythm, for which no pacing is delivered because the VRR indicated pacing interval is at a lower rate than the sensed intrinsic ventricular beats.

5        The third, fourth, and fifth ventricular beats represent the onset of atrial fibrillation, resulting in erratic ventricular rates. The third ventricular beat is sensed well before expiration of the VRR indicated pacing interval  $T_2$ , such that no pacing pulse is issued. For the sensed third ventricular beat, filter 515 computes the new VRR indicated pacing interval  $T_3$  as being shorter in duration relative to the previous  
10 VRR indicated pacing interval  $T_2$ .

      The fourth ventricular beat is similarly sensed well before expiration of the VRR indicated pacing interval  $T_3$ , such that no pacing pulse is issued. For the sensed fourth ventricular beat, filter 515 computes the new VRR indicated pacing interval  $T_4$  as being shorter in duration relative to the previous VRR indicated pacing  
15 interval  $T_3$ .

      The fifth ventricular beat is sensed before expiration of the VRR indicated pacing interval  $T_4$ , such that no pacing pulse is issued. For the sensed fifth ventricular beat, filter 515 computes the new VRR indicated pacing interval  $T_5$  as being shorter in duration relative to the previous VRR indicated pacing interval  $T_4$ .

20        The sixth, seventh, and eighth ventricular beats indicate regularization of the ventricular rate using the pacing techniques described above. No ventricular beat is sensed during the VRR indicated pacing interval  $T_5$ , so a pacing pulse is issued to evoke the sixth ventricular beat. A new VRR indicated pacing interval  $T_6$  is computed as being increased in duration relative to the previous VRR indicated  
25 pacing interval  $T_5$ , lowering the VRR indicated rate. Similarly, no ventricular beat is sensed during the VRR indicated pacing interval.

      The ninth ventricular beat represents another erratic ventricular beat resulting from the atrial fibrillation episode. The ninth ventricular beat is sensed before expiration of the VRR indicated pacing interval  $T_6$ . As a result, a shorter new VRR  
30 indicated pacing interval  $T_7$  is computed.



The tenth and eleventh ventricular beats illustrate further regularization of the ventricular rate using the pacing techniques described above. No ventricular beat is sensed during the VRR indicated pacing interval  $T_9$ , so a pacing pulse is issued to evoke the tenth ventricular beat. A new VRR indicated pacing interval  $T_{10}$  is computed as being increased in duration relative to the previous VRR indicated pacing interval  $T_9$ , lowering the VRR indicated rate. Similarly, no ventricular beat is sensed during the VRR indicated pacing interval  $T_{10}$ , so a pacing pulse is issued to evoke the tenth ventricular beat. A new VRR indicated pacing interval  $T_{11}$  is computed as being increased in duration relative to the previous VRR indicated pacing interval  $T_{10}$ , lowering the VRR indicated rate.

The twelfth, thirteenth, fourteenth, and fifteenth ventricular beats illustrate resumption of a stable intrinsic rhythm after termination of the atrial fibrillation episode. For such a stable rate, the VRR indicated rate proceeds asymptotically toward a "floor value" that tracks, but remains below, the intrinsic rate. This allows the intrinsic heart signals to control heart rate when such intrinsic heart signals provide a stable rhythm. As a result, when the patient's intrinsic rate is constant, paces will be withheld, allowing the patient's intrinsic heart rhythm to continue. If the patient's heart rate includes some variability, and the VRR indicated floor value is close to the mean intrinsic heart rate, then occasional paced beats will occur. Such pace beats will gradually lengthen the VRR indicated pacing interval, thereby allowing subsequent intrinsic behavior when the patient's heart rate becomes substantially constant.

The intrinsic coefficient  $a$  of filter **515** controls the "attack slope" of the VRR indicated heart rate as the VRR indicated heart rate increases because of sensed intrinsic beats. The paced coefficient  $b$  of filter **515** controls the "decay slope" of the VRR indicated heart rate as the VRR indicated heart rate decreases during periods of paced beats. In one embodiment, in which  $a > 1.0$  and  $b > 1.0$ , decreasing the value of  $a$  toward 1.0 increases the attack slope such that the VRR indicated rate increases faster in response to sensed intrinsic beats, while decreasing the value of  $b$  toward 1.0 decreases the decay slope such that the VRR indicated rate

decreases more slowly during periods of paced beats. Conversely, for  $a > 1.0$  and  $b > 1.0$ , increasing the value of  $a$  from 1.0 decreases the attack slope such that the VRR indicated rate increases more slowly in response to sensed intrinsic beats, while increasing the value of  $b$  from 1.0 increases the decay slope such that the

5 VRR-indicated rate decreases more quickly during periods of paced beats.

In one embodiment, for  $a > 1.0$  and  $b > 1.0$ , decreasing both  $a$  and  $b$  toward 1.0 increases VRR indicated rate during periods of sensed intrinsic activity so that the VRR indicated rate is closer to the mean intrinsic rate. Because the VRR indicated rate is closer to the mean intrinsic rate, variability in the intrinsic heart rate  
10 is more likely to trigger paces at the VRR indicated rate. On the other hand, for  $a > 1.0$  and  $b > 1.0$ , increasing both  $a$  and  $b$  from 1.0 decreases the VRR indicated rate during periods of sensed intrinsic activity so that the VRR indicated rate is farther beneath the mean intrinsic rate. Because the VRR indicated rate is farther beneath the mean intrinsic rate, the same variability in the intrinsic heart rate becomes less  
15 likely to trigger paces at the VRR indicated rate.

In one embodiment, these coefficients are programmable by the user, such as by using remote programmer 125. In another embodiment, the user selects a desired performance parameter (e.g., desired degree of rate regularization, desired attack slope, desired decay slope, etc.) from a corresponding range of possible values, and  
20 device 105 automatically selects the appropriate combination of coefficients of filter 515 to provide a filter setting that corresponds to the selected user-programmed performance parameter, as illustrated generally by Table 2. Other levels of programmability or different combinations of coefficients may also be used.

25

30

Table 2. *Example of Automatic Selection of Aspects of Filter Setting Based on a User-Programmable Performance Parameter.*

5	User-Programmable Performance Parameter	Intrinsic Coefficient $a$	Paced Coefficient $b$
10	1 (Less Rate Regularization)	2.0	3.0
	2	1.8	2.6
	3	1.6	2.2
	4	1.4	1.8
	5	1.2	1.4
	6 (More Rate Regularization)	1.0	1.0

15

#### Filter Rate Behavior Example 2

Figure 12 is a graph illustrating generally, by way of example, but not by way of limitation, one embodiment of selecting between more than one indicated pacing interval. Figure 12 is similar to Figure 11 in some respects, but Figure 12 includes a second indicated pacing interval. In one embodiment, the first indicated pacing interval is the VRR indicated pacing interval, described above, and the second indicated pacing interval is a sensor indicated pacing interval, from an accelerometer, minute ventilation, or other indication of the patient's physiological need for increased cardiac output.

In one embodiment, a selected indicated pacing interval is based on the shorter of the first and second indicated pacing intervals. Stated differently, device 105 provides pacing pulses at the higher indicated pacing rate. In the example illustrated in Figure 12, first and second beats and the twelfth through fifteenth beats are paced at the sensor indicated rate, because it is higher than the VRR indicated rate and the intrinsic rate. The third, fourth, fifth, and ninth beats are sensed intrinsic beats that are sensed during the shorter of either of the VRR and sensor

indicated pacing intervals. The sixth through eighth beats and tenth and eleventh beats are paced at the VRR indicated rate, because it is higher than the sensor indicated rate. Also, for these beats, no intrinsic beats are sensed during the VRR indicated intervals. In one embodiment, the above-described equations for filter 515  
5 operate to increase the VRR indicated rate toward the sensor-indicated rate when the sensor indicated rate is greater than the VRR indicated rate, as illustrated by first through third and twelfth through fifteenth beats in Figure 12. In an alternate embodiment, however,  $T_n = b \cdot w \cdot VV_n + (1-w) \cdot T_{n-1}$ , if  $VV_n$  is concluded by a VRR indicated paced beat, and  $T_n = T_{n-1}$  if  $VV_n$  is concluded by a sensor indicated paced  
10 beat, thereby leaving the VRR indicated rate unchanged for sensor indicated paced beats.

In this embodiment, the ranges of both the sensor indicated rate and the VRR indicated rate are limited so that they do not extend to rates higher than the URL or to rates lower than the LRL. In one embodiment, the LRL and the URL are  
15 programmable by the user, such as by using remote programmer 125.

In a further embodiment, the selected indicated pacing interval is based on the shorter of the first and second indicated pacing intervals only if an atrial tachyarrhythmia, such as atrial fibrillation, is present. Otherwise, the second indicated pacing interval is used, as described above.

### 20 Filter Rate Behavior Example 3

Figure 13 is a graph illustrating generally, by way of example, but not by way of limitation, another illustrative example of heart rate vs. time according to a spreadsheet simulation of the behavior of the above-described VRR algorithm. In Figure 13, the VRR algorithm is turned off until time 130. Stable intrinsic lower  
25 rate behavior is modeled for times between 0 and 10 seconds. Erratic intrinsic ventricular rates, such as would result from atrial tachyarrhythmias including atrial fibrillation, are modeled during times between 10 seconds and 130 seconds. At time 130 seconds, the VRR algorithm is turned on. While some erratic intrinsic beats are subsequently observed, the VRR algorithm provides pacing that is expected to  
30 substantially stabilize the heart rate, as illustrated in Figure 13. The VRR indicated

pacing rate gradually decreases until intrinsic beats are sensed, which results in a slight increase in the VRR indicated pacing rate. Thus, the VRR algorithm favors the patient's intrinsic heart rate when it is stable, and paces at the VRR indicated heart rate when the patient's intrinsic heart rate is unstable. It is noted that Figure 13 does not represent clinical data, but rather provides a simulation model that illustrates one example of how the VRR algorithm is expected to operate.

#### Filter Example 4

In one embodiment, filter 515 includes variable coefficients such as, for example, coefficients that are a function of heart rate (or its corresponding time interval). In one example, operation of the filter 515 is described by  $T_n = a \cdot w \cdot VV_n + (1-w) \cdot T_{n-1}$ , if  $VV_n$  is concluded by an intrinsic beat, otherwise is described by  $T_n = b \cdot w \cdot VV_n + (1-w) \cdot T_{n-1}$ , if  $VV_n$  is concluded by a paced beat, where at least one of  $a$  and  $b$  are linear, piecewise linear, or nonlinear functions of one or more previous V-V intervals such as, for example, the most recent V-V interval,  $VV_n$ .

Figure 14 is a graph illustrating generally, by way of example, but not by way of limitation, one embodiment of using at least one of coefficients  $a$  and  $b$  as a function of one or more previous V-V intervals such as, for example, the most recent V-V interval  $VV_n$ . In one such example,  $a$  is less than 1.0 when  $VV_n$  is at or near the lower rate limit (e.g., 1000 millisecond interval or 60 beats/minute), and  $a$  is greater than 1.0 when  $VV_n$  is at or near the upper rate limit (e.g., 500 millisecond interval or 120 beats/minute). For a constant  $b$ , using a smaller value of  $a$  at lower rates will increase the pacing rate more quickly for sensed events; using a larger value of  $a$  at higher rates increases the pacing rate more slowly for sensed events. In another example,  $b$  is close to 1.0 when  $VV_n$  is at or near the lower rate limit, and  $b$  is greater than 1.0 when  $VV_n$  is at or near the upper rate limit. For a constant  $a$ , using a smaller value of  $b$  at lower rates will decrease the pacing rate more slowly for paced events; using a larger value of  $b$  at higher rates decreases the pacing rate more quickly for paced events.

#### Conclusion

It is to be understood that the above description is intended to be illustrative,

and not restrictive. Many other embodiments will be apparent to those of skill in the art upon reviewing the above description. The scope of the invention should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

WHAT IS CLAIMED IS:

1. A method, including:
  - obtaining V-V intervals between ventricular beats;
  - computing a first indicated pacing interval based at least on a most recent V-V interval duration and a previous value of the first indicated pacing interval; and
  - providing pacing therapy, based on the first indicated pacing interval.
2. The method of claim 1, in which computing the first indicated pacing interval includes:
  - adjusting the first indicated pacing interval, by an amount based at least on the most recent V-V interval duration and the previous value of the first indicated pacing interval, if the most recent V-V interval is concluded by an intrinsic beat; and
  - increasing the first indicated pacing interval, by an amount based at least on the most recent V-V interval duration and the previous value of the first indicated pacing interval, if the most recent V-V interval is concluded by a paced beat.
3. The method of claim 2, in which:
  - adjusting the first indicated pacing interval includes obtaining a first average of the most recent V-V interval and the previous value of the first indicated pacing interval; and
  - increasing the first indicated pacing interval includes obtaining a second average of the most recent V-V interval and the previous value of the first indicated pacing interval.
4. The method of claim 3, in which:
  - obtaining the first average includes:
    - applying a first weight to the most recent V-V interval; and
    - applying a second weight to the previous value of the first indicated pacing interval, in which the second weight is different from the first weight;

obtaining the second average includes:

applying a third weight to the most recent V-V interval; and

applying a fourth weight to the previous value of the first indicated pacing interval, in which the fourth weight is different from the third weight.

5. The method of claim 4, in which the first weight is different from the third weight.

6. The method of claim 1, in which computing the first indicated pacing interval ( $T_n$ ) is carried out according to  $T_n = A \cdot VV_n + B \cdot T_{n-1}$ , where  $A$  and  $B$  are coefficients,  $VV_n$  is the most recent V-V interval duration, and  $T_{n-1}$  is the previous value of the first indicated pacing interval.

7. The method of claim 6, in which  $A$  and  $B$  are different values.

8. The method of claim 6, in which computing the first indicated pacing interval ( $T_n$ ) is carried out according to:  $T_n = A \cdot VV_n + B \cdot T_{n-1}$ , if  $VV_n$  is concluded by an intrinsic beat, otherwise is carried out according to  $T_n = C \cdot VV_n + D \cdot T_{n-1}$ , if  $VV_n$  is concluded by a paced beat, where  $C$  and  $D$  are coefficients.

9. The method of claim 8, in which  $C$  and  $D$  are different values.

10. The method of claim 9, in which  $C$  and  $A$  are different values.

11. The method of claim 8, in which at least one of  $A$ ,  $B$ ,  $C$ , and  $D$  is a function of heart rate.

12. The method of claim 1, in which computing the first indicated pacing interval ( $T_n$ ) is carried out according to  $T_n = a \cdot w \cdot VV_n + (1-w) \cdot T_{n-1}$ , where  $a$  and  $w$  are coefficients,  $VV_n$  is the most recent V-V interval duration, and  $T_{n-1}$  is the previous



value of the first indicated pacing interval.

13. The method of claim 12, in which  $a$  is greater than a value selected from the group consisting of 0.5 and 1.0.

14. The method of claim 13, in which  $a$  is approximately equal to 1.1.

15. The method of claim 12, in which computing the first indicated pacing interval ( $T_n$ ) is carried out according to:  $T_n = a \cdot w \cdot VV_n + (1-w) \cdot T_{n-1}$ , if  $VV_n$  is concluded by an intrinsic beat, otherwise is carried out according to  $T_n = b \cdot w \cdot VV_n + (1-w) \cdot T_{n-1}$ , if  $VV_n$  is concluded by a paced beat, where  $b$  is a coefficient.

16. The method of claim 15, in which  $a$  and  $b$  are different values.

17. The method of claim 16, in which  $a$  is greater than a value selected from the group consisting of 0.5 and 1.0.

18. The method of claim 17, in which  $b$  is greater than  $a$ .

19. The method of claim 16, in which  $b$  is greater than  $a$ .

20. The method of claim 16, in which  $a$  is approximately equal to 1.1 and  $b$  is approximately equal to 1.2.

21. The method of claim 15, in which at least one of  $a$ ,  $b$ , and  $w$  are a function of heart rate.

22. The method of claim 12, in which  $w$  is approximately between 0 and 1.



pacing interval, if the most recent V-V interval is concluded by an intrinsic beat; and  
increasing the first indicated pacing interval, by an amount based at least on  
the most recent V-V interval duration and the previous value of the first indicated  
pacing interval, if the most recent V-V interval is concluded by a paced beat.

30. The method of claim 29, in which:  
adjusting the pacing interval includes obtaining a first average of the most  
recent V-V interval and the previous value of the first indicated pacing interval; and  
increasing the pacing interval includes obtaining a second average of the  
most recent V-V interval and the previous value of the first indicated pacing  
interval.

31. The method of claim 30, in which:  
obtaining the first average includes:  
applying a first weight to the most recent V-V interval; and  
applying a second weight to the previous value of the first indicated  
pacing interval, in which the second weight is different from the first weight;  
obtaining the second average includes:  
applying a third weight to the most recent V-V interval; and  
applying a fourth weight to the previous value of the first indicated  
pacing interval, in which the fourth weight is different from the third weight.

32. The method of claim 31, in which the first weight is different from the third  
weight.

33. The method of claim 28, in which computing the first indicated pacing  
interval ( $T_n$ ) is carried out according to  $T_n = A \cdot VV_n + B \cdot T_{n-1}$ , where  $A$  and  $B$  are  
coefficients,  $VV_n$  is the most recent V-V interval duration, and  $T_{n-1}$  is the previous  
value of the first indicated pacing interval.

34. The method of claim 33, in which  $A$  and  $B$  are different values.
35. The method of claim 33, in which computing the first indicated pacing interval ( $T_n$ ) is carried out according to:  $T_n = A \cdot VV_n + B \cdot T_{n-1}$ , if  $VV_n$  is concluded by an intrinsic beat, otherwise is carried out according to  $T_n = C \cdot VV_n + D \cdot T_{n-1}$ , if  $VV_n$  is concluded by a paced beat, where  $C$  and  $D$  are coefficients.
36. The method of claim 35, in which  $C$  and  $D$  are different values.
37. The method of claim 36, in which  $C$  and  $A$  are different values.
38. The method of claim 35, in which at least one of  $A$ ,  $B$ ,  $C$ , and  $D$  are a function of heart rate.
39. The method of claim 28, in which computing the first indicated pacing interval ( $T_n$ ) is carried out according to  $T_n = a \cdot w \cdot VV_n + (1-w) \cdot T_{n-1}$ , where  $a$  and  $w$  are coefficients,  $VV_n$  is the most recent V-V interval duration, and  $T_{n-1}$  is the previous value of the first indicated pacing interval.
40. The method of claim 39, in which  $a$  is greater than a value selected from the group consisting of 0.5 and 1.0.
41. The method of claim 40, in which  $a$  is approximately equal to 1.1.
42. The method of claim 39, in which computing the first indicated pacing interval ( $T_n$ ) is carried out according to:  $T_n = a \cdot w \cdot VV_n + (1-w) \cdot T_{n-1}$ , if  $VV_n$  is concluded by an intrinsic beat, otherwise is carried out according to  $T_n = b \cdot w \cdot VV_n + (1-w) \cdot T_{n-1}$ , if  $VV_n$  is concluded by a paced beat, where  $b$  is a coefficient.
43. The method of claim 42, in which  $a$  and  $b$  are different values.

44. The method of claim 43, in which  $a$  is greater than 1.
45. The method of claim 44, in which  $b$  is greater than  $a$ .
46. The method of claim 43, in which  $b$  is greater than  $a$ .
47. The method of claim 43, in which  $a$  is approximately equal to 1.1 and  $b$  is approximately equal to 1.2.
48. The method of claim 42, in which  $w$  is approximately between 0 and 1.
49. The method of claim 42, in which at least one of  $a$ ,  $b$ , and  $w$  is a function of heart rate.
50. The method of claim 28, in which providing pacing therapy is also based on a second indicated pacing interval that is based on a sensor.
51. The method of claim 50, in which providing pacing therapy is based on the shorter of the first and second indicated pacing intervals.
52. The method of claim 51, in which the first and second indicated pacing intervals do not fall outside a range bounded by intervals corresponding to upper and lower rate limits.
53. The method of claim 28, in which computing the first indicated pacing interval includes limiting the minimum first indicated pacing interval to be longer than or equal to an interval corresponding to an upper rate limit.

54. The method of claim 28, in which computing the first indicated pacing interval includes limiting the maximum first indicated pacing interval to be shorter than or equal to an interval corresponding to a lower rate limit.

55. A method of providing pacing therapy to a heart, the method including:  
detecting an atrial fibrillation;  
obtaining V-V intervals between ventricular beats;  
computing a first indicated pacing interval ( $T_n$ ) according to:  $T_n = a \cdot w \cdot VV_n + (1-w) \cdot T_{n-1}$ , if  $VV_n$  is concluded by an intrinsic beat, otherwise computing  $T_n$  according to  $T_n = b \cdot w \cdot VV_n + (1-w) \cdot T_{n-1}$ , if  $VV_n$  is concluded by a paced beat, where  $a$ ,  $b$ , and  $w$  are coefficients,  $VV_n$  is a most recent V-V interval duration, and  $T_{n-1}$  is a previous value of the first indicated pacing interval; and  
providing pacing therapy, based on the first indicated pacing interval, when the atrial fibrillation is present.

56. The method of claim 55, in which at least one of  $a$ ,  $b$ , and  $w$  is a function of heart rate.

57. The method of claim 55, in which  $a$  is approximately equal to 1.1,  $b$  is approximately equal to 1.2, and  $w$  is approximately equal to 1/16.

58. A cardiac rhythm management system, including:  
a ventricular sensing circuit for sensing ventricular beats;  
a controller, obtaining V-V intervals between ventricular beats and computing a first indicated pacing interval based at least on a most recent V-V interval duration and a previous value of the first indicated pacing interval; and  
a ventricular therapy circuit, providing pacing therapy based on the first indicated pacing interval.

59. The system of claim 58, in which the controller adjusts the first indicated pacing interval, by an amount based at least on the most recent V-V interval duration and the previous value of the first indicated pacing interval, if the most recent V-V interval is concluded by an intrinsic beat, and the controller increases the first indicated pacing interval, by an amount based at least on the most recent V-V interval duration and the previous value of the first indicated pacing interval, if the most recent V-V interval is concluded by a paced beat.

60. The system of claim 58, in which the controller computes the first indicated pacing interval ( $T_n$ ) according to:  $T_n = a \cdot w \cdot VV_n + (1-w) \cdot T_{n-1}$ , if  $VV_n$  is concluded by an intrinsic beat, otherwise  $T_n$  is computed according to  $T_n = b \cdot w \cdot VV_n + (1-w) \cdot T_{n-1}$ , if  $VV_n$  is concluded by a paced beat, where  $b$  is a coefficient.

61. The system of claim 60, in which at least one of  $a$ ,  $b$ , and  $w$  is a function of heart rate.

62. The system of claim 58, further including a sensor, and in which the controller computes a second indicated pacing interval based on signals received from the sensor, and in which the ventricular therapy circuit provides pacing therapy that is also based on the second indicated pacing interval.

63. A cardiac rhythm management system, including:  
a ventricular sensing circuit;  
a controller, the controller including:  
a V-V interval timer;  
a first register, for storing a first indicated pacing interval;  
a filter, updating the first indicated pacing interval based on the V-V interval timer and the first register; and  
a ventricular therapy circuit, providing pacing therapy based at least partially on the first indicated pacing interval.

64. The system of claim 63, further including a sensor, and in which the controller further includes a second register, for storing a second indicated pacing interval that is based on a signal received from the sensor, and in which the ventricular therapy circuit provides pacing therapy based on one or more of the first and second indicated pacing intervals.

65. The system of claim 64, further including an atrial sensing circuit and an atrial tachyarrhythmia detection module, and in which the selection module selects the first indicated pacing interval as the selected indicated pacing interval during an atrial tachyarrhythmia.

66. The system of claim 65, in which the selection module selects the second indicated pacing interval as the selected indicated pacing interval when no atrial tachyarrhythmia is detected.

67. The system of claim 64, in which the filter includes an infinite impulse response (IIR).

68. The system of claim 64, in which the filter includes a finite impulse response (FIR).

69. The system of claim 64, in which the filter includes an averager.

70. The system of claim 69, in which the filter includes a weighted averager.

71. The system of claim 63, in which the filter updates the first indicated pacing interval ( $T_n$ ) according to  $T_n = A \cdot VV_n + B \cdot T_{n-1}$ , where  $A$  and  $B$  are coefficients,  $VV_n$  is the V-V interval duration provided by the V-V interval timer, and  $T_{n-1}$  is the previous value of the first indicated pacing interval.



72. The system of claim 71, in which  $A$  and  $B$  are different values.
73. The system of claim 71, in which the filter updates the first indicated pacing interval ( $T_n$ ) according to:  $T_n = A \cdot VV_n + B \cdot T_{n-1}$ , if  $VV_n$  is concluded by an intrinsic beat, otherwise is updated according to  $T_n = C \cdot VV_n + D \cdot T_{n-1}$ , if  $VV_n$  is concluded by a paced beat, where  $C$  and  $D$  are coefficients.
74. The system of claim 73, in which at least one of  $A$ ,  $B$ ,  $C$ , and  $D$  is a function of heart rate.
75. The system of claim 74, in which  $C$  and  $D$  are different values.
76. The system of claim 74, in which  $C$  and  $A$  are different values.
77. The system of claim 73, in which the filter updates the first indicated pacing interval ( $T_n$ ) according to  $T_n = a \cdot w \cdot VV_n + (1-w) \cdot T_{n-1}$ , where  $a$  and  $w$  are coefficients,  $VV_n$  is the V-V interval duration provided by the V-V interval timer, and  $T_{n-1}$  is the previous value of the first indicated pacing interval.
78. The system of claim 77, in which  $a$  is greater than a value selected from the group consisting of 0.5 and 1.0.
79. The system of claim 78, in which  $a$  is approximately equal to 1.1.
80. The system of claim 77, in which the filter updates the first indicated pacing interval ( $T_n$ ) according to:  $T_n = a \cdot w \cdot VV_n + (1-w) \cdot T_{n-1}$ , if  $VV_n$  is concluded by an intrinsic beat, otherwise the filter updates  $T_n$  according to  $T_n = b \cdot w \cdot VV_n + (1-w) \cdot T_{n-1}$ , if  $VV_n$  is concluded by a paced beat, where  $b$  is a coefficient.

81. The system of claim 80, in which at least one of  $a$ ,  $b$ , and  $w$  is a function of heart rate.

82. The system of claim 80, in which  $a$  and  $b$  are different values.

83. The system of claim 82, in which  $a$  is greater than 1.

84. The system of claim 83, in which  $b$  is greater than  $a$ .

85. The system of claim 82, in which  $b$  is greater than  $a$ .

86. The system of claim 82, in which  $a$  is approximately equal to 1.1 and  $b$  is approximately equal to 1.2.

87. The system of claim 80, in which  $w$  is approximately between 0 and 1.

88. The system of claim 63, further including a leadwire adapted for coupling at least one of the ventricular sensing circuit and the ventricular therapy circuit to a heart.

89. The system of claim 63, further comprising a remote programmer, adapted for communication with the controller.

90. An implantable cardiac rhythm management device, including:  
a ventricular sensing circuit;  
an atrial sensing circuit, for detecting an atrial tachyarrhythmia;  
a sensor;  
a controller, the controller including:  
a V-V interval timer;  
a first register, for storing a first indicated pacing interval;

an infinite impulse response (IIR) filter that updates the first indicated pacing interval ( $T_n$ ) according to:  $T_n = A \cdot VV_n + B \cdot T_{n-1}$ , if  $VV_n$  is concluded by an intrinsic beat, otherwise is updated according to  $T_n = C \cdot VV_n + D \cdot T_{n-1}$ , if  $VV_n$  is concluded by a paced beat, where  $A$ ,  $B$ ,  $C$  and  $D$  are coefficients, and  $VV_n$  is the V-V interval duration provided by the V-V interval timer, and  $T_{n-1}$  is the previous value of the first indicated pacing interval;

a second register, for storing a second indicated pacing interval that is based on a signal received from the sensor; and

a selection module, selecting the shorter of the first and second indicated pacing intervals, when an atrial tachyarrhythmia is detected, to provide a selected indicated pacing interval, and selecting the second indicated pacing interval, when no atrial tachyarrhythmia is detected; and a ventricular therapy circuit, providing pacing therapy based on the selected indicated pacing interval.

**91. A cardiac rhythm management system, including:**

a ventricular sensing circuit;

a controller, the controller including:

a V-V interval timer;

a first register, for storing a first indicated pacing interval;

means for updating the first indicated pacing interval; and

a ventricular therapy circuit, providing pacing therapy based at least partially on the first indicated pacing interval.

**Method and Apparatus for Treating Irregular Ventricular Contractions Such  
As During Atrial Arrhythmia**

**Abstract**

A cardiac rhythm management system is capable of treating irregular ventricular heart contractions, such as during atrial tachyarrhythmias such as atrial fibrillation. A first indicated pacing interval is computed based at least partially on  
5 a most recent V-V interval duration between ventricular beats and a previous value of the first indicated pacing interval. Pacing therapy is provided based on either the first indicated pacing interval or also based on a second indicated pacing interval, such as a sensor-indicated pacing interval. A weighted averager such as an infinite impulse response (IIR) filter adjusts the first indicated pacing interval for sensed  
10 beats and differently adjusts the first indicated pacing interval for paced beats. The system regularizes ventricular rhythms by pacing the ventricle, but inhibits pacing when the ventricular rhythms are stable.

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Printed Name SUNEEL ARORA

Signature Suneel Arora

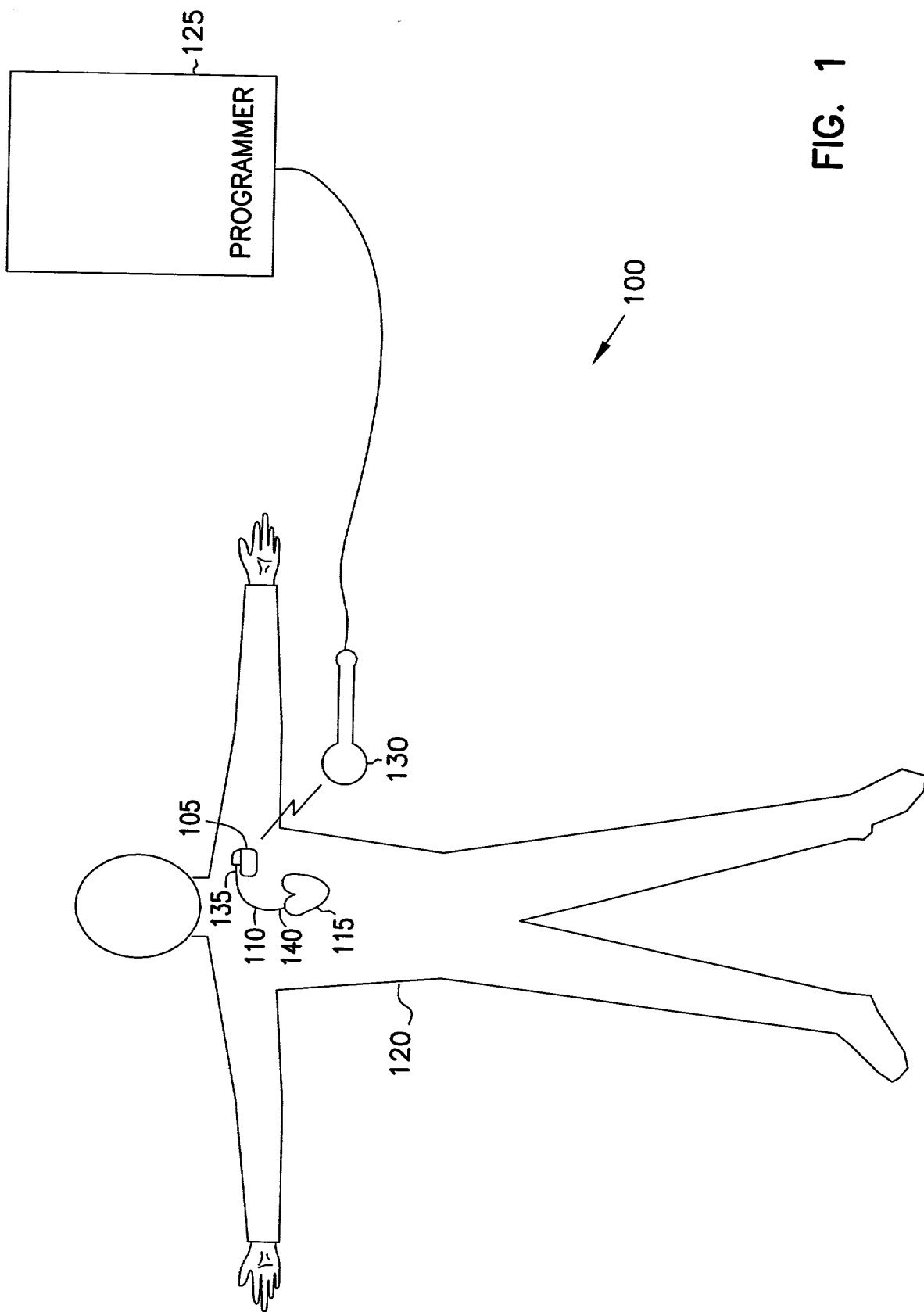
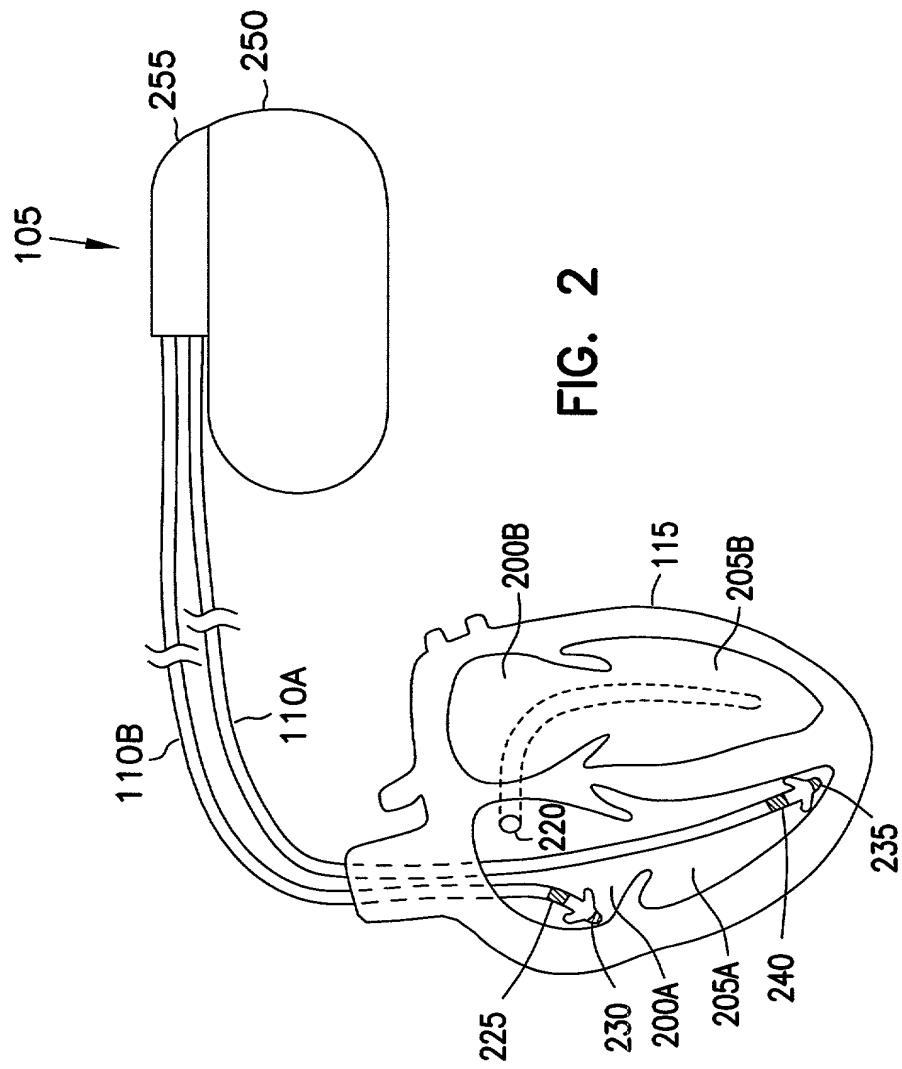


FIG. 1



**FIG. 2**

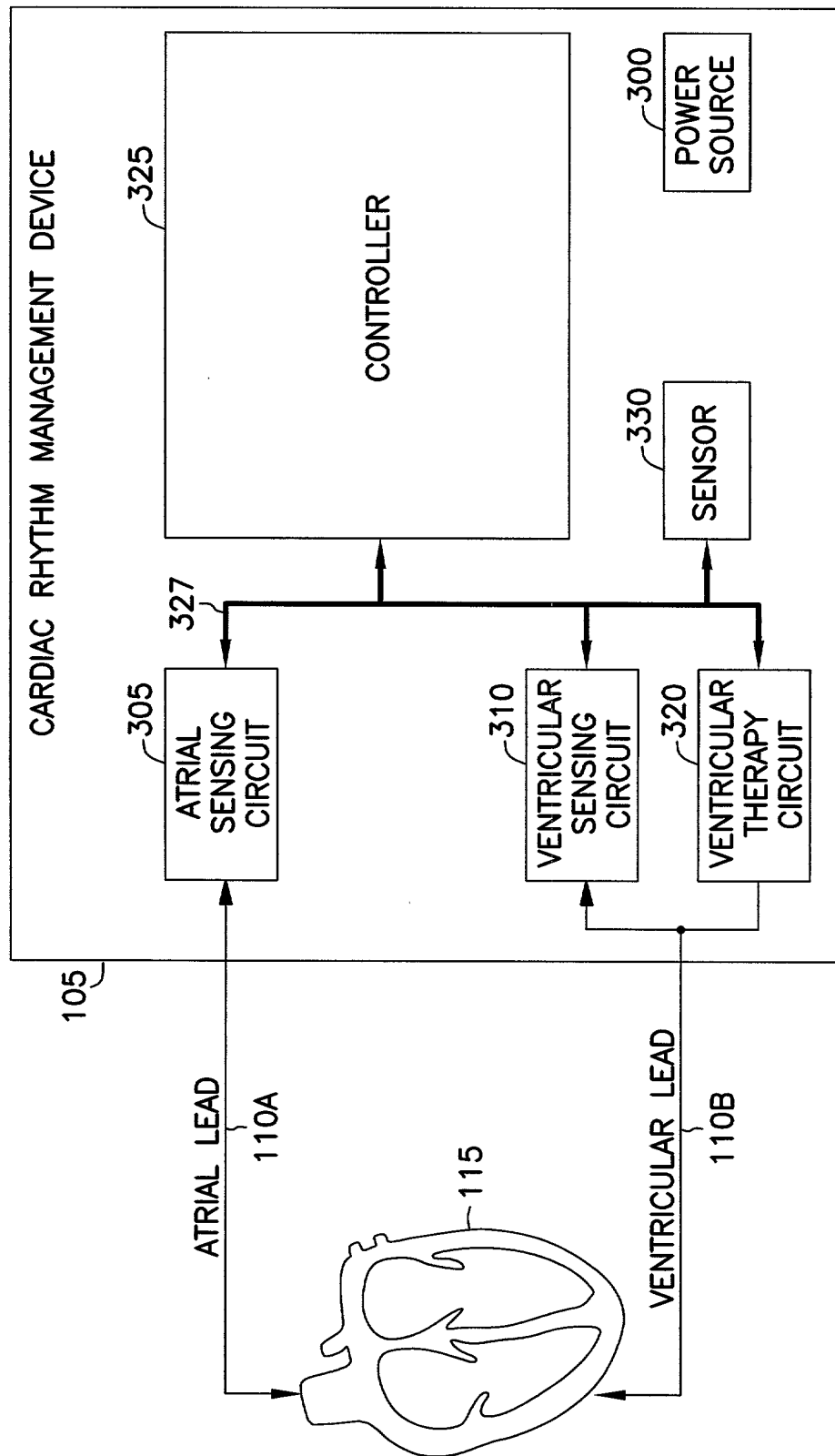


FIG. 3

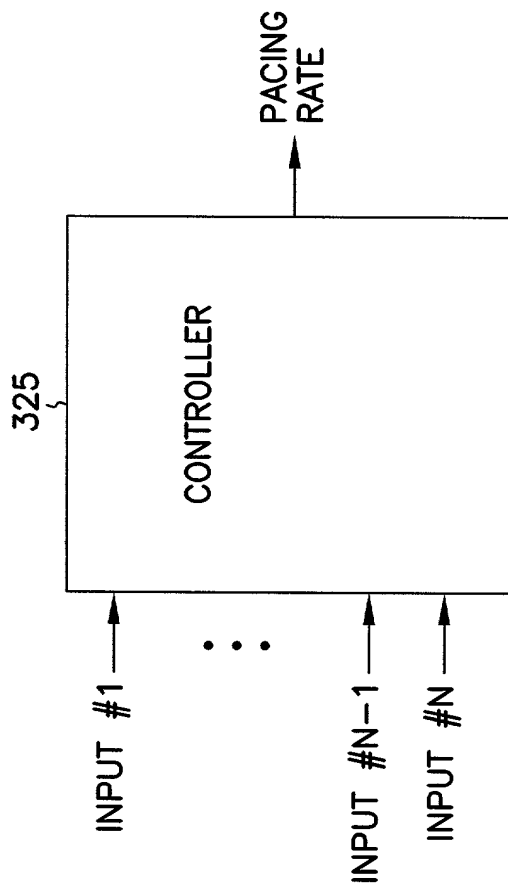


FIG. 4



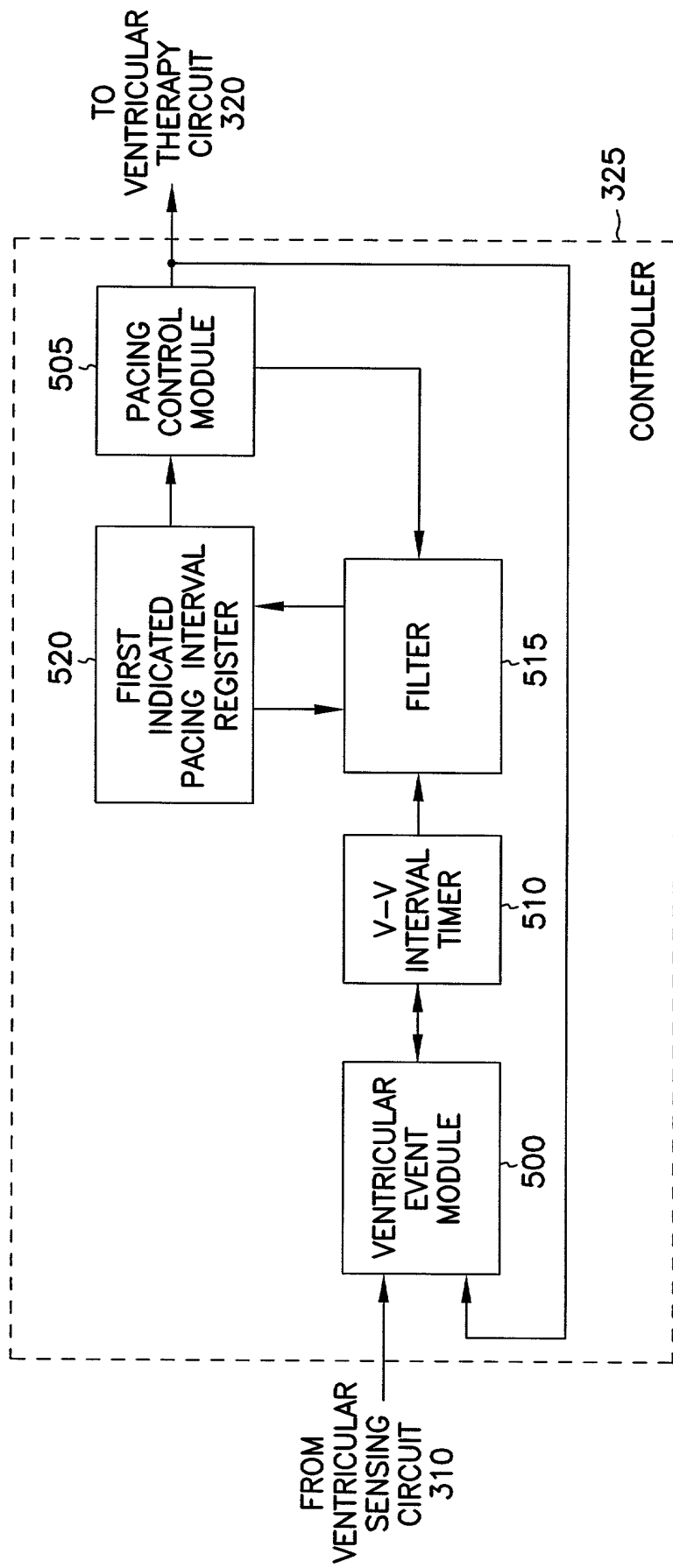


FIG. 5

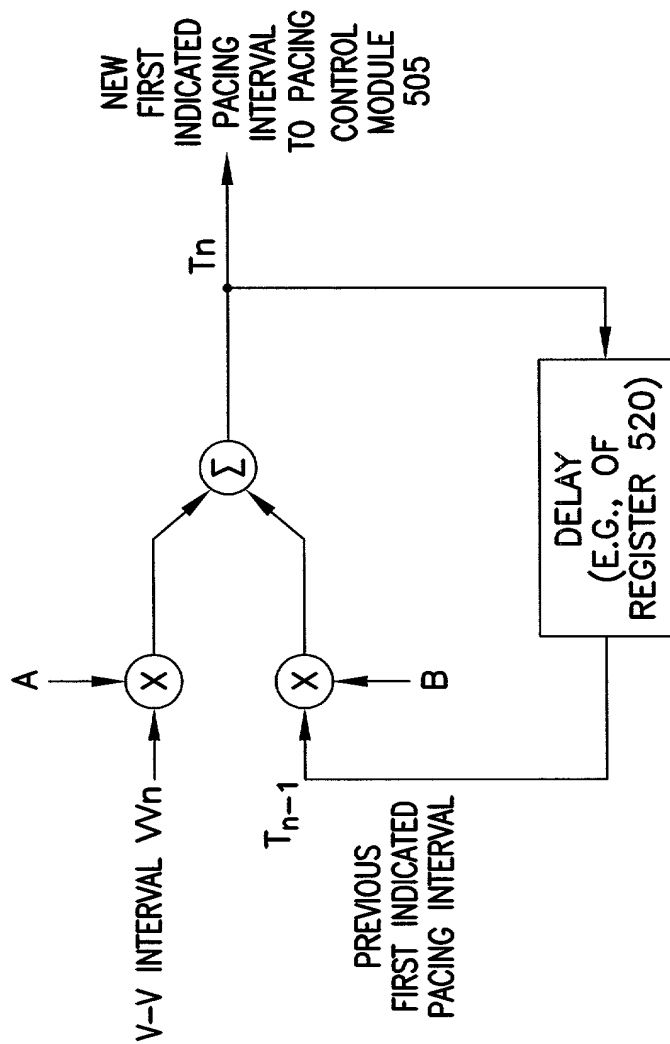


FIG. 6

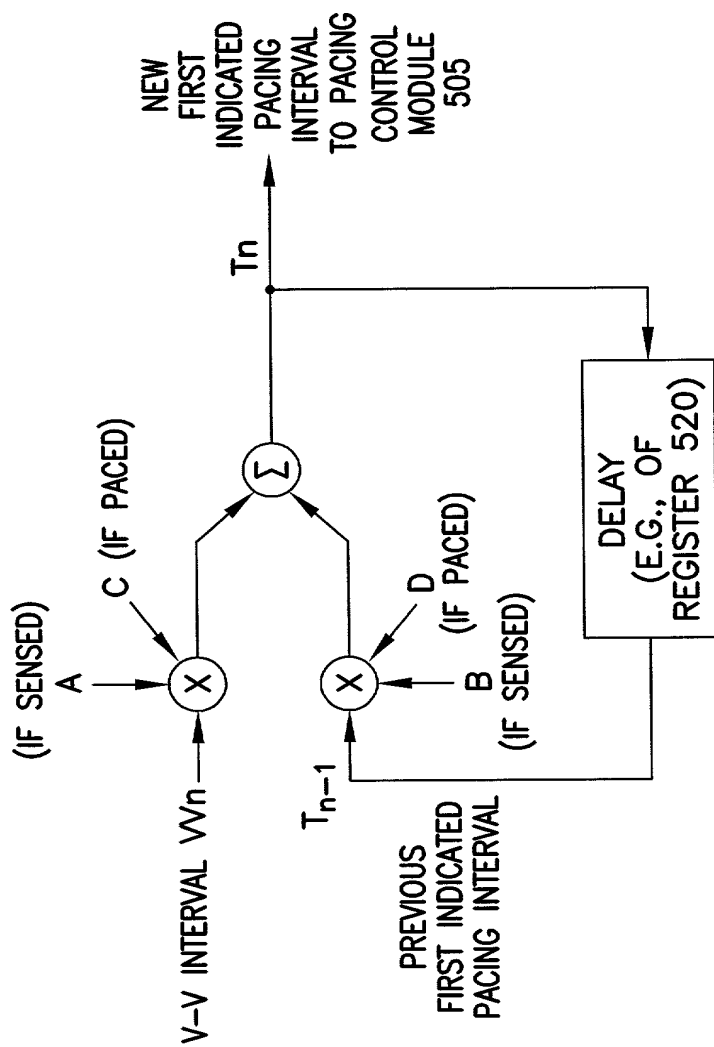


FIG. 7

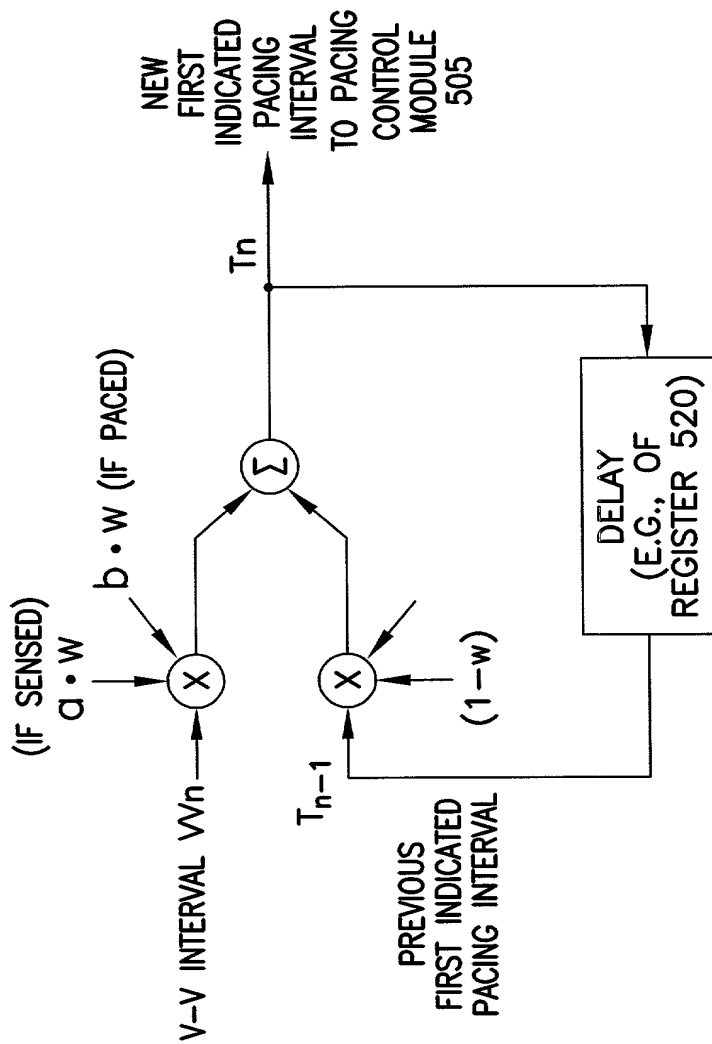
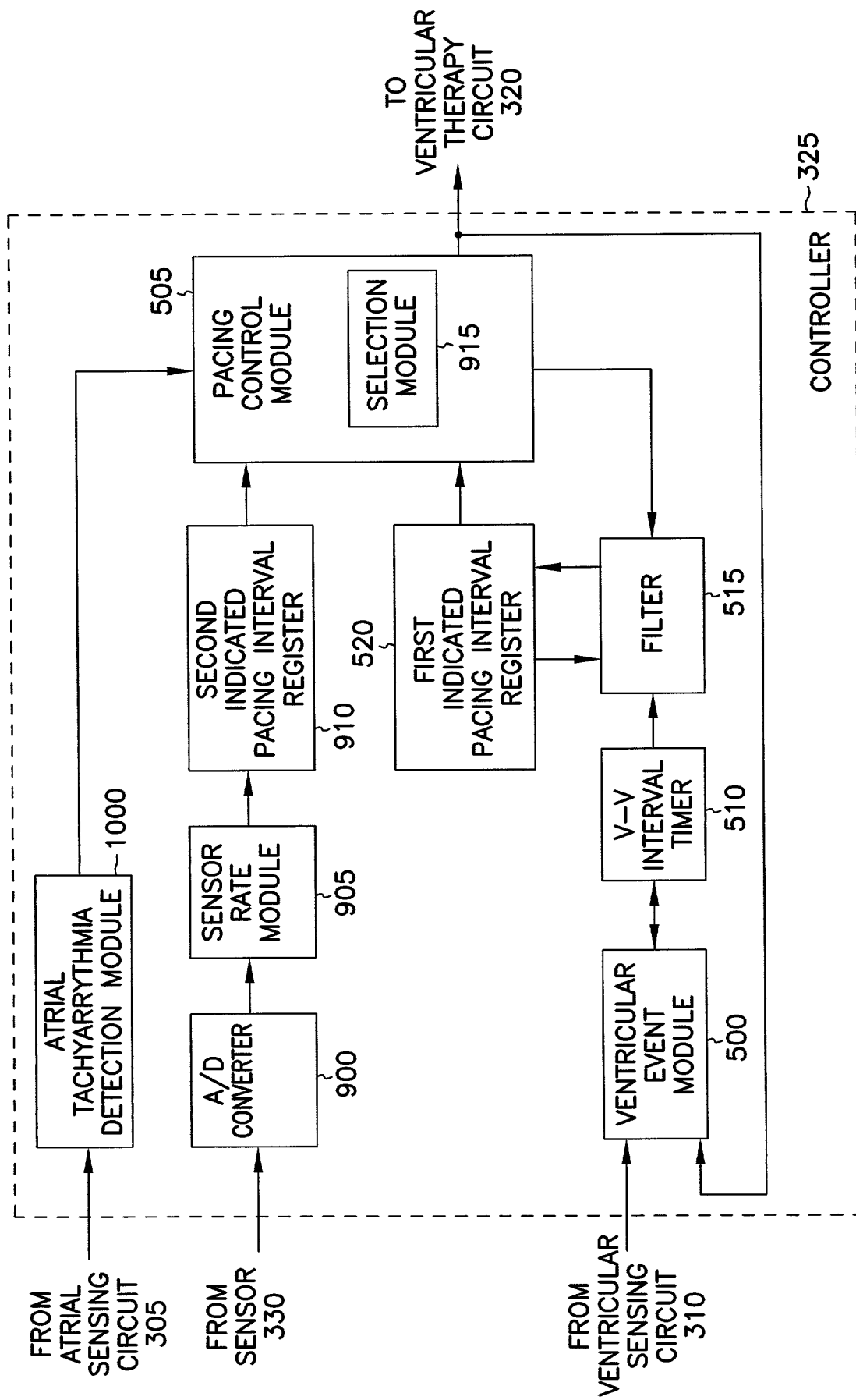


FIG. 8





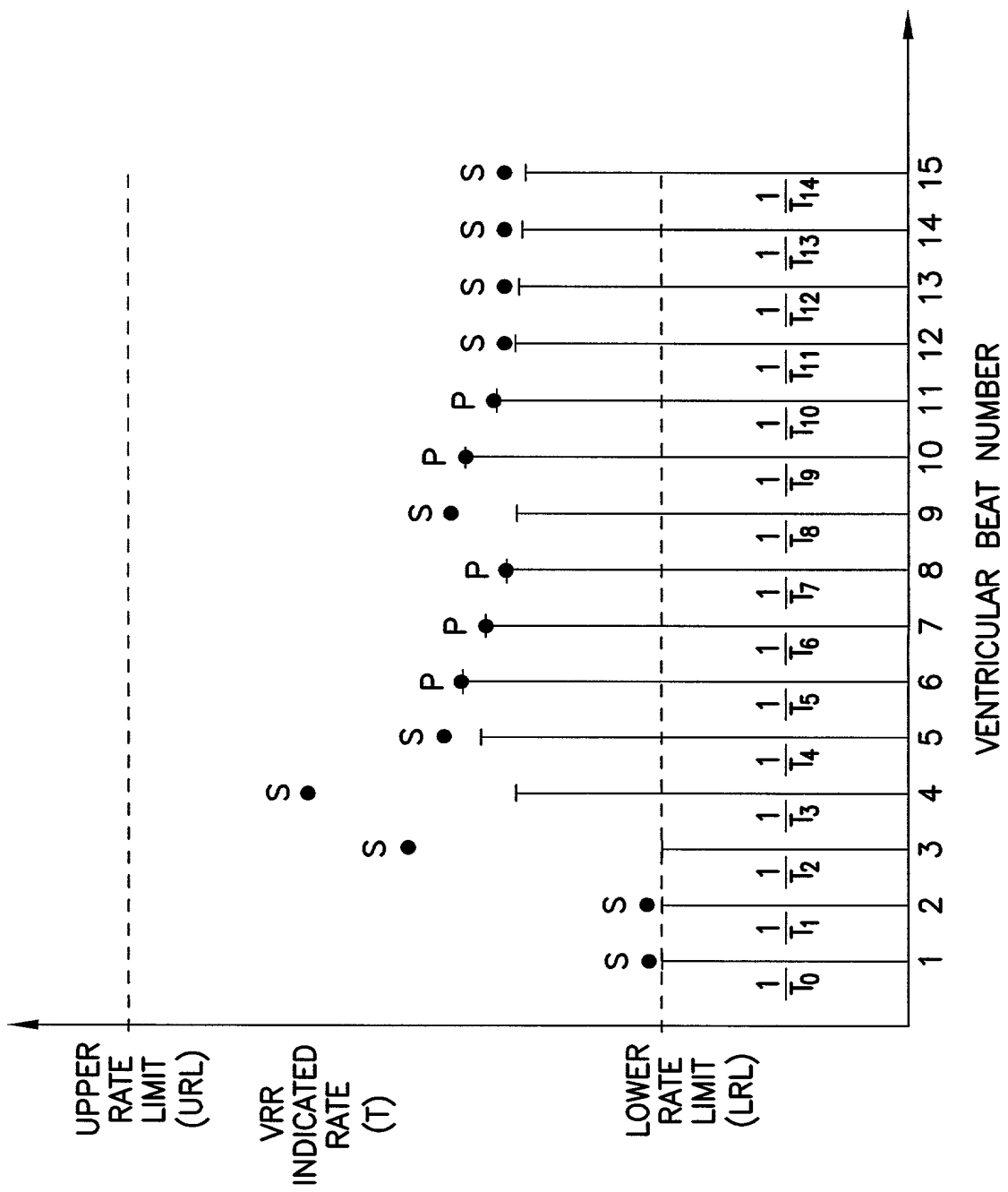


FIG. 11

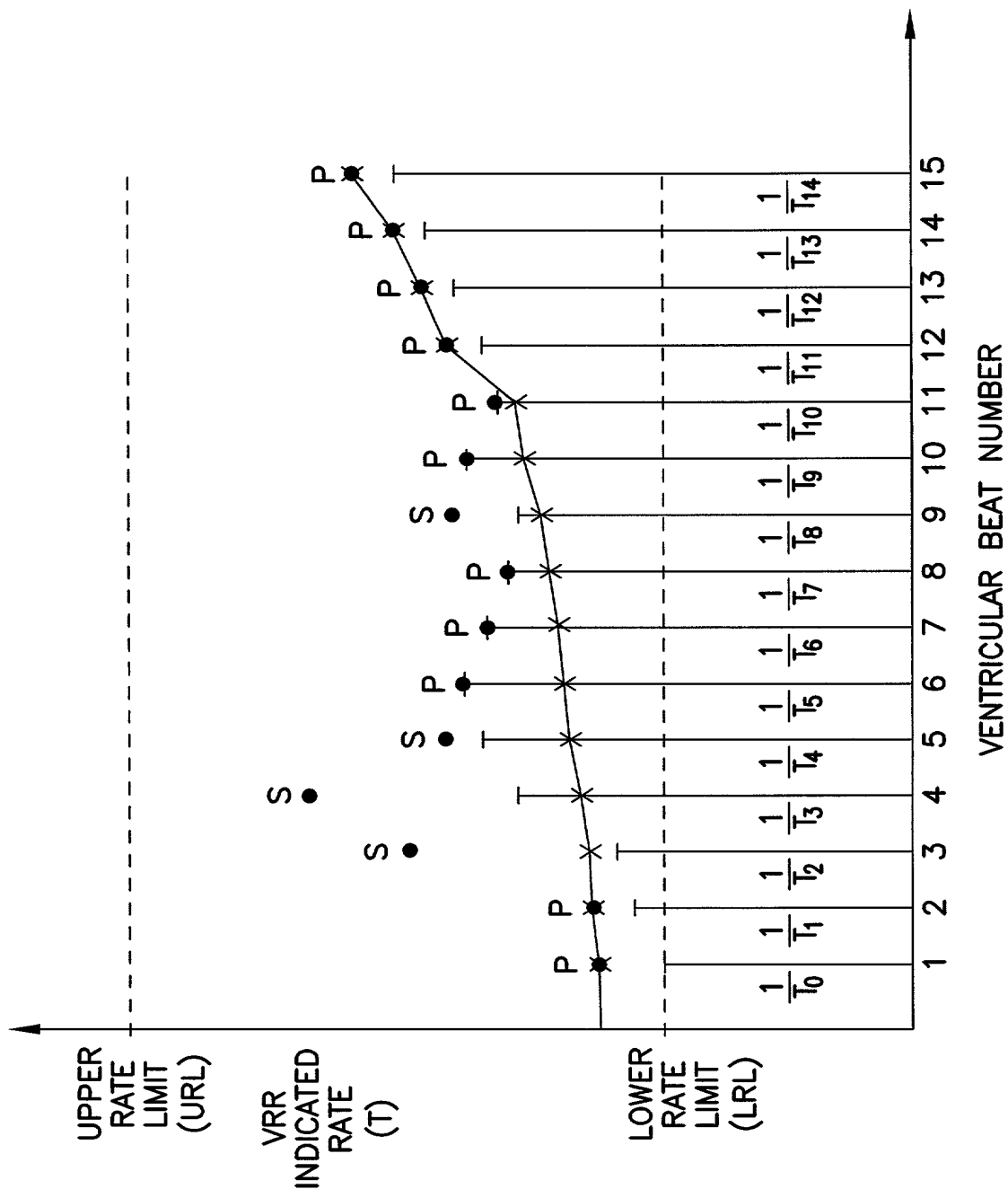
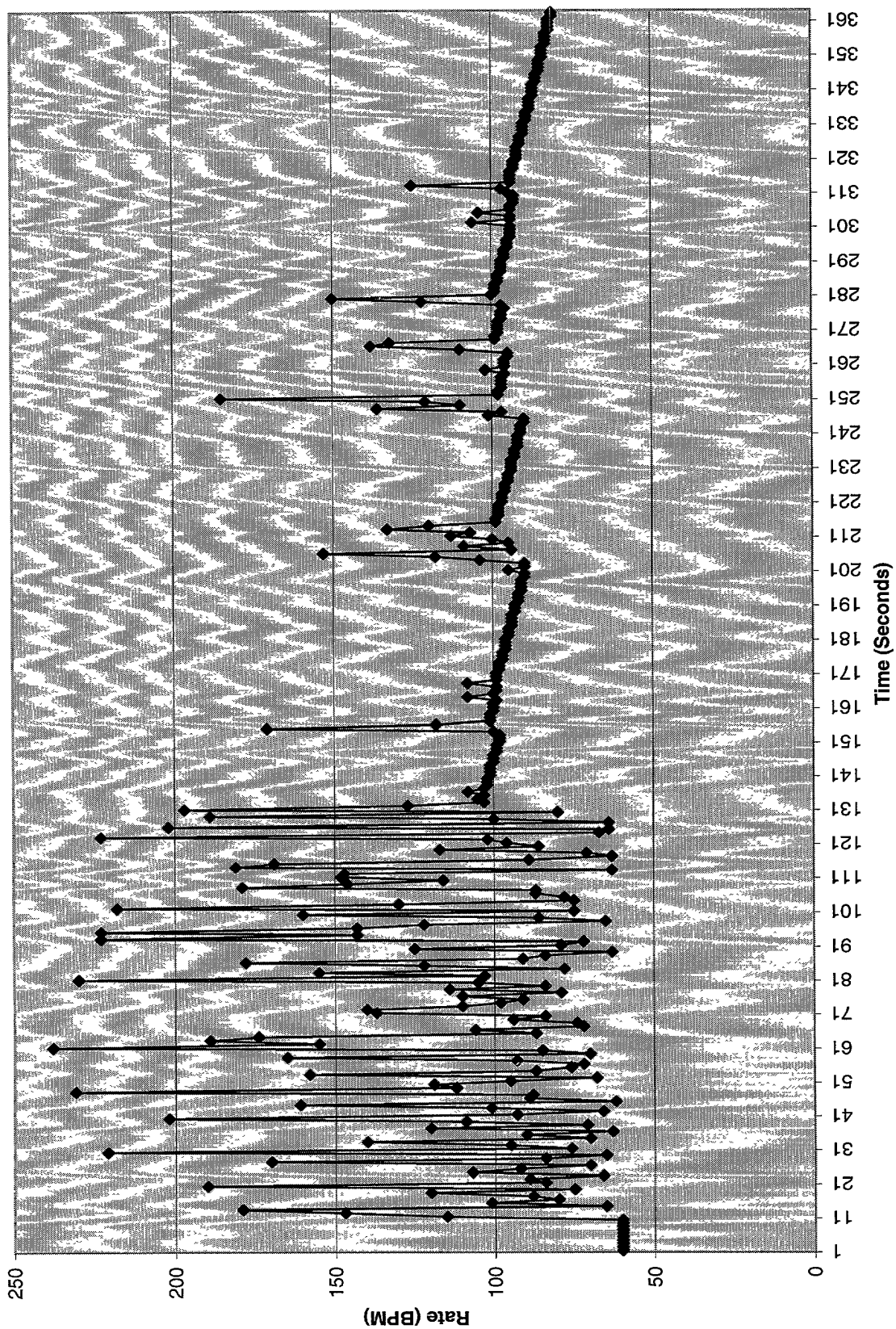


FIG. 12



—◆— Rate



**FIG. 13**

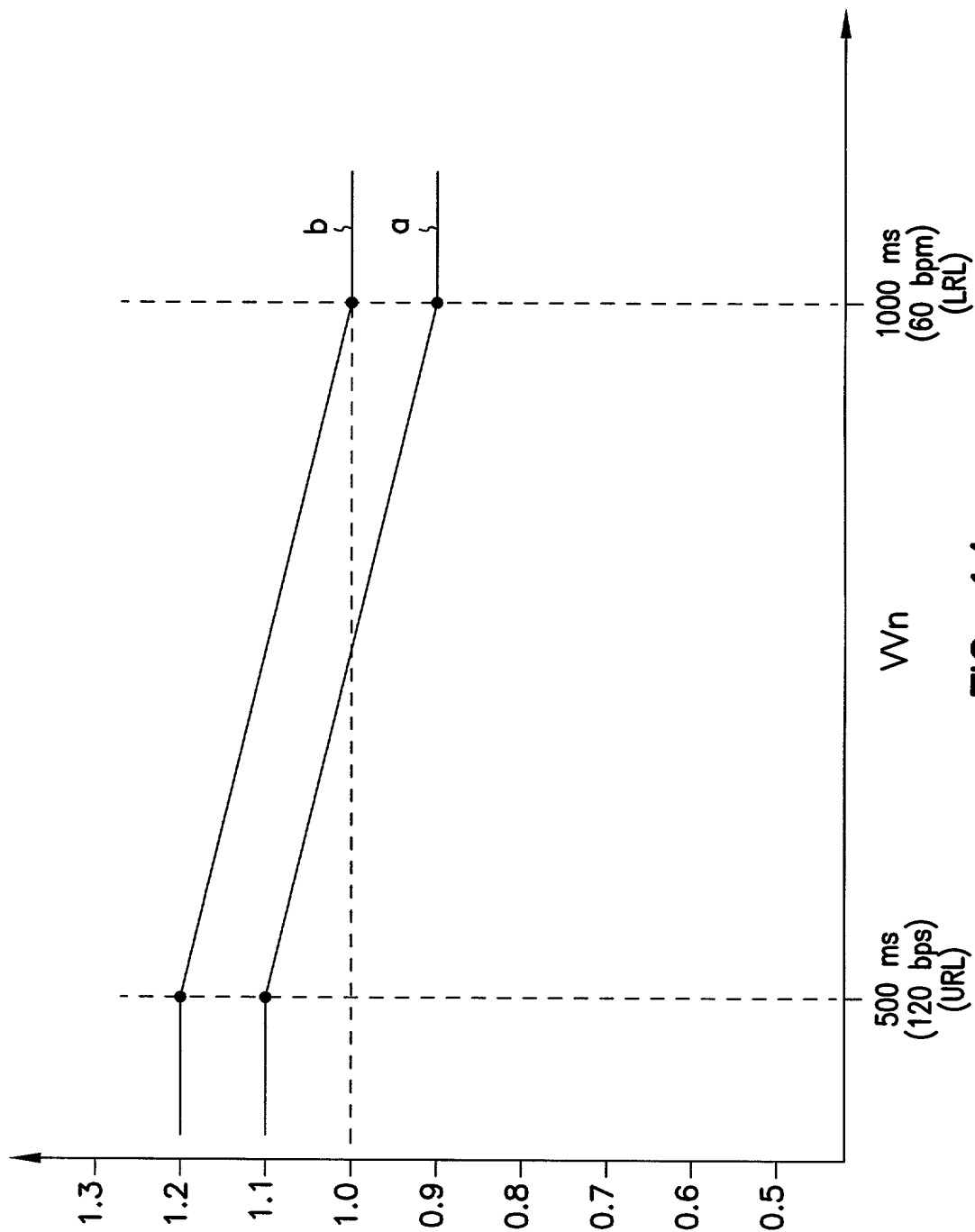


FIG. 14

# United States Patent Application

## COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: **METHOD AND APPARATUS FOR TREATING IRREGULAR VENTRICULAR CONTRACTIONS SUCH AS DURING ATRIAL ARRHYTHMIA.**

The specification of which is attached hereto.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56 (see page 3 attached hereto). I also acknowledge my duty to disclose all information known to be material to patentability which became available between a filing date of a prior application and the national or PCT international filing date in the event this is a Continuation-In-Part application in accordance with Title 37, Code of Federal Regulations § 1.63(e).

I hereby claim foreign priority benefits under Title 35, United States Code, § 119/365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

**No such claim for priority is being made at this time.**

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below.

**No such claim for priority is being made at this time.**

I hereby claim the benefit under Title 35, United States Code, § 120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

**No such claim for priority is being made at this time.**

I hereby appoint the following attorney(s) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

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Clark, Barbara J.	Reg. No. 38,107	Lacy, Rodney L.	Reg. No. 41,136	Sieffert, Kent J.	Reg. No. 41,312
Drake, Eduardo E.	Reg. No. 40,594	Leffert, Thomas W.	Reg. No. 40,697	Slifer, Russell D.	Reg. No. 39,838
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Embretson, Janet E.	Reg. No. 39,665	Litman, Mark A.	Reg. No. 26,390	Terry, Kathleen R.	Reg. No. 31,884
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Fordenbacher, Paul J.	Reg. No. 42,546	Mack, Lisa K.	Reg. No. 42,825	Woessner, Warren D.	Reg. No. 30,440

I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/organization/who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Schwegman, Lundberg, Woessner & Kluth, P.A. to the contrary.

Please direct all correspondence in this case to Schwegman, Lundberg, Woessner & Kluth, P.A. at the address indicated below:

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Telephone No. (612)373-6900

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Jeffrey E. Stahmann

Date: \_\_\_\_\_

21-May-99

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
  - (i) Opposing an argument of unpatentability relied on by the Office, or
  - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
- (2) Each attorney or agent who prepares or prosecutes the application; and
- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.